

PHYLLIS BENNETT (Executor of the Estate of
HARVEY BENNETT); ARTHUR J. OLSTAD;
KATHLEEN OLSTAD; ROBERT PERKINS;
ELIZABETH CLARK; WILLIAM MURPHY;
BONNIE MURPHY; RITA WEAVER;
MARVIN BAUMAN; ROWENA BAUMAN;
HENRY ACKERMAN; GENIEVE
ACKERMAN; DONALD HACKERSON;
CAROLYN HACKERSON; JAMES WALZ;
MARY BETH WALZ; JUDITH COTE;
THEODORE ALMOND; EDWARD J. MILLER,
JR.; THOMAS HEPLER; BARBARA KING;
SAMUEL KING; RICKEY THOMAS;
CAROLYN THOMAS; JOHN ACKERMAN;
KIM ACKERMAN; ALBERT DELSANTRO;
CHARLOTTE DELSANTRO; RICHARD
BRESSETTE; RALPH BOOTH; HANS
OMASTA; WINONA OMASTA; EDDIE
BATES; LINDA BATES; CHARLES DAVID
SMEDLEY; MARCHETTE COOK (Personal
Representative of the Estate of ALICE
SOUTHERLAND); TY BEARD; VERNON
DEBOARD (Personal Representative of the
Estate of KATHERINE DEBOARD); JOHN A.
DAVIS JR.; DEBORAH DAVIS; KENNETH
COLLINS; KIM COLLINS; CAROLYN
HARRISON (Personal Representative of the
Estate of GERALD HARRISON); KAY ANN
RICE; ROBERT RICE; LOIS RONCAL;
DARLENE HERONEMA; KATHERINE
WOLLASTON; DANIEL WOLLASTON;
GEORGE CHOSICH; ELIZABETH CHOSICH;
PEGGY BROWN; MARY ANN MINASIAN;
LEE ALVIN SMITH; MARY PARKER; BRIAN
SUKENIK; LINDA BRUNNER; DENNIS
WORKMAN; MARY WATERS; GEORGE
SCHMIDT; SHARON SCHMIDT; CLINTON
HUMPHREY; TENNA HUMPHREY; BETTY
BOSTIC; JIMMY BOSTIC; GEORGIA
SUTTON; BRAHA JACKSON; ROBERT
MASON; NOEL CLECKLER; FRANCES

CLECKLER; MARK LAGANELLI, (Personal
Representative of the Estate of LAWRENCE
LAGANELLI); NEILS DAVIS; DON
AMBURGEY; JOYCE AMBURGEY; ELBERT
CROWDER; TIMOTHY LEROSE;
MARGARET LEROSE; DOYLE TURNER,
(Personal Representative of the Estate of
CAROLYN TURNER); MELVIN KINNEY;
ISABELLA KINNEY; BALDEMAR
MARTINEZ; ANNA MARTINEZ; ALBERT
SHEPHERD (Personal Representative of the
Estate of EMILY SHEPHERD); DORIS
JOHNSON; FRED BURROUGH; MONA
WINDHAM; RONNIE WINDHAM; WILLIAM
HUNT; PHYLLIS HUNT; PINK JONES; ANNIE
JONES; MARY DAVIS; JAMES MASON;
CATHY MASON; CECIL THOMAS; DEBBIE
THOMAS; MARTHA SUE DIXON; BELVA
WARD; DONALD BARD; JUDY BARD; JOHN
SPAULDING, JR.; LINDA SPAULDING;
SHIRLEY MILLER; RONALD MILLER;
JACQUELINE FABBRI (Personal Representative
of the Estate of FRANK FABBRI); INGA
REYNOLDS (Personal Representative of the
Estate of GERWIN HERMENA); CARLETTA
WILLIAMS (Personal Representative of the
Estate of JAMES C. WILLIAMS, III); TRIO
CALDWELL; BEVERLY CALDWELL; EDWIN
STREED; MARGARET STREED; DIANNE
CRUCE; DOUG HYAK; DAMEON
ALBRITTON; JI YONG AHN ALBRITTON;
LAUREL TURLEY; ROGER TURLEY; DIANE
MANCINELLI; CONNIE LUYE (Personal
Representative of the Estate of EVELYN MOSS);
ROBERT E. SMITH; DORLIS LYLE (Personal
Representative of the Estate of JAMES LYLE);
GEORGE L. BUSH; EDWIN MARTIN;
CHARLES HERSHISER; MARY FRANCES
HERSHISER; SHELBY CAMPBELL; PENNY
WATSON (Personal Representative of the Estate
of DARWIN WATSON); JOHN HENDRIX;
LINDA PERRY;

Plaintiffs

v.

TEVA PHARMACEUTICALS USA, INC.; and

DOES 1-50, Inclusive,

Defendants,

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The Plaintiffs listed above, for Plaintiffs' Complaint and Demand for Jury Trial against Defendants TEVA PHARMACEUTICALS USA, INC. and DOES 1-50, inclusive (collectively referred to throughout this Complaint as "Defendants" or "Teva" unless otherwise indicated), allege as follows¹:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Phyllis Bennett

a) Phyllis Bennett, individually and as Executor of the Estate of Harvey Bennett, deceased, (hereinafter "Mrs. Bennett") is an individual who resides in Coweta County, Georgia. Mr. Bennett was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced pulmonary fibrosis, a life-threatening and debilitating condition. In December, 2014, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he

¹ The allegations as to the individual Plaintiffs are based on the individual personal knowledge of the individual Plaintiffs listed below. Other allegations are on information and belief, which facts are likely to have evidentiary support after a reasonable opportunity for investigation and discovery.

receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In December 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Nimish Dhruva prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Nimish Dhruva was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that

Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January, 2015, he began to experience many of the symptoms outlined in the Medication Guide, which include increased heart rate, shortness of breath, extreme exhaustion, coughing, difficulty breathing, anxiousness, and bleeding complications. His chest x-ray and CT results prior to taking Amiodarone in December 2014, were found to be normal.

h) In approximately February 2015 he was admitted to the hospital with an initial diagnosis of respiratory distress, A-Fib and swelling of extremities. Soon thereafter, in March 2015 he began to develop worsened difficulty breathing and was diagnosed with multiple, consecutive pneumonias as well vision complications. Eventually as his condition worsened, several high definition CT scans of his lungs were performed, which progressively worsened each time. After spending several months in and out of the hospital, he was discharged with a diagnosis of pulmonary fibrosis and respiratory failure and congestive heart failure and excessive bleeding. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damages, scarred and thickened,

making it difficult for lungs to work properly. In April 2015, he was admitted to the hospital once again for pneumonia and respiratory failure and was placed on BiPaP, to assist with breathing. He was debilitated, and was suffering from multiple infections, excessive bleeding, anemia, and he was too unstable to receive interventions. As a result he died from complications on April 17, 2015.

i) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

j) Before developing pulmonary fibrosis, he was a healthy and active individual. He spent a great deal of time with his family and enjoyed many outdoor activities, as well as helping with housework. Only a few months later, after starting Amiodarone, his quality of life was significantly impaired, and much of his time was spent in and out of rehabilitation centers and hospitals, where he developed several infections and complications.

2. **Plaintiffs Arthur J. Olstad and Kathleen Olstad**

a) Plaintiff Arthur J. Olstad (hereinafter "Plaintiff" or Olstad") is an individual who resides in Kane County, Illinois. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced lung toxicity, a life-threatening and debilitating condition. In or around November 2014, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced lung toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening

complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In November 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. McCarthy and Dr. Severino prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. McCarthy and Dr. Severino were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required

Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2015, he began to experience many of the symptoms outlined in the Medication Guide, which include difficulty breathing, decreased lung volume, coughing, fatigue, weakness, difficulty walking, nausea, and an irregular heartrate. After several hospital admissions and treatment for pneumonia, he was presented with a diagnosis of Amiodarone Induced Lung Toxicity. Lung Toxicity is a debilitating, chronic condition that makes it very difficult to breathe, and drastically reduces quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing lung toxicity, he was a remarkably healthy and active individual. After developing lung toxicity, he could not walk on his own. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone induced lung toxicity such as hypothyroid disease, kidney disease and an enlarged heart.

j) Additionally, Plaintiff, Kathleen Olstad, is the spouse of the Plaintiff Arthur Olstad, and resides with her spouse, and she depended on Art Olstad to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Art Olstad, Plaintiff Kathleen Olstad has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

3. **Plaintiff Robert Perkins**

a) Plaintiff Robert Perkins (hereinafter "Plaintiff" or Perkins") is an individual who resides in Hamilton County, Ohio. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced pulmonary fibrosis, a life-threatening and debilitating condition. In November 2011, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced respiratory failure, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In February 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Teva and potentially other manufacturers, Dr. Mickelson prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mickelson was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially

other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately June 2016, he began to experience e shortness of breath, irregular heart rate, difficulty breathing, fatigue, weakness, anxiousness, depression, and elevated liver enzymes. In June of 2016, he had been admitted to the hospital with an initial diagnosis of atypical bilateral pneumonia, and chronic respiratory failure. The doctor treating him discontinued his use of Amiodarone. As his condition rapidly deteriorated, several high definition CT scans were performed, which revealed atypical interstitial pneumonia, diaphragm paralysis, pulmonary edema and hemorrhage, as well as airspace disease. After spending nearly two weeks in the hospital, including time in ICU requiring breathing assistance devices such as BiPap, or CPAP, as well as full time oxygen he was discharged with a diagnosis of chronic respiratory failure. His severe restrictive lung disease requires in-home nursing care, physical therapy, and the use of oxygen 24 hours per day, this condition limits his mobility and quality of life significantly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced respiratory failure, he was a very active and healthy individual. He spent a great deal of time enjoying his family members. He was a hard worker, employed full time as a bus driver for Hertz. After his discharge from the hospital, he has become disabled and required to leave his employment. He now struggles just to talk without losing his breath. He also suffers from a litany of other health problems related to his use of Amiodarone, including left lung paralysis, heart failure, abnormal thyroid function, and abnormal liver enzymes.

4. **Plaintiff Elizabeth Clark**

a) Plaintiff Elizabeth Clark, (hereinafter "Plaintiff" or "Clark") is an individual who resides in Hale County, Texas. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced pulmonary fibrosis, a life-threatening and debilitating condition. In August 2002, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she

receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In August 2002, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. John Zias prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. John Zias who was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not

receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately July 2015, she began to experience shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. She was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damages, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, she was a remarkably healthy and active individual. After developing pulmonary fibrosis, she could not walk across the room. She also developed vision problems and suffers from a litany of other health

problems related to her use of Amiodarone and medications used to treat her Amiodarone induced pulmonary fibrosis.

5. **Plaintiffs William Murphy and Bonnie Murphy**

a) Plaintiff William Murphy (hereinafter “Plaintiff” or Murphy”) is an individual who resides in Hamilton County, Ohio. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced lung toxicity, a life-threatening and debilitating condition. In or around May 2008, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced lung toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around April of 2008 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Eugene

Chung prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by the Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Eugene Severino was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was

not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately May 2012, he began to experience difficulty breathing, irregular heart rate, hypertension, abnormal bleeding, and vision deterioration, fatigue, and weakness. After several hospital admissions and treatment for pneumonia, atrial fibrillation, and pulmonary hypertension, he was presented with a diagnosis of Amiodarone Induced Lung Toxicity. Lung Toxicity is a debilitating, chronic condition that makes it very difficult to breathe, and drastically reduces the quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing lung toxicity, he was a remarkably healthy and active individual. He enjoyed spending quality time with his wife and children. After developing lung toxicity, he could not breathe without full time use of oxygen. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone induced lung toxicity such as bleeding abnormalities, pulmonary hypertension, vision loss and complications, anemia, and an enlarged heart.

j) Additionally, Plaintiff, Bonnie Murphy is the spouse of the Plaintiff William Murphy, and resides with her spouse, and she depended on William Murphy to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff William Murphy, Plaintiff Bonnie Murphy has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

6. **Plaintiff Rita M. Weaver**

a) Plaintiff, Rita Weaver (hereinafter “Plaintiff” or “Weaver”) is an individual who resides in Mobile County, Alabama. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In October 2015, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In October 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Gerry Phillips prescribed her a course of 200 mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone

manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Gerry Phillips was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately October 2015, she began to experience loss of vision, tingling in hands and feet, loss of hair and nails, muscle and joint pain and shortness of breath. She was presented with a diagnosis of pulmonary fibrosis and loss of vision. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, she was a remarkably healthy and active individual. After developing pulmonary fibrosis, she is unable to walk without a walker and wakes up gasping for air, caused by Amiodarone use. She has lost her hair and nails and has developed rashes that made her skin peel off and she suffers from a litany of other health problems apparently related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

7. **Plaintiffs Marvin Bauman and Rowena Bauman**

a. Plaintiff, Marvin Bauman (hereinafter "Plaintiff" or "Bauman") is an individual who resides in Laurel County, Kentucky. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In December 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed

Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b. At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c. Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d. In December 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth, along with the continuing sales efforts of Defendants, Dr. Marwan Mihyu prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Chalhoub was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e. He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his

prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f. In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g. In approximately July 2016, he began to experience shortness of breath, extreme fatigue, dizziness, sleep apnea and edema. He was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h. He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i. Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he became extremely weak and became short of breath walking across the room. He developed sleep apnea and edema and he suffers from a litany of other health problems apparently related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j. Additionally, Plaintiff, Rowena Bauman is the spouse of the Plaintiff Marvin Bauman, and resides with her spouse, and she depended on Plaintiff, Marvin Bauman to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff, Marvin Bauman, Plaintiff, Rowena Bauman has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

8. **Plaintiffs Henry Ackerman and Genieve Ackerman**

a) Plaintiff Henry Ackerman (hereinafter "Plaintiff" or Ackerman") is an individual who resides in Muscogee County, Georgia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Ischemic Optic Neuropathy, which is a debilitating condition related to the eyes resulting in blindness and reduced loss of vision. In or around August 2014, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Optic Neuropathy in both eyes, ultimately losing vision entirely to his right eye, and partially in his left eye. He received no warning from his physician about these potential severe degenerative complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around August 2014 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Mahesh Patel prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mahesh Patel was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva

and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately October 2014, he began to experience vision loss, optic nerve damage, degenerative vision changes, and blindness. After several medical evaluations and treatments for visual complications, he was presented with a diagnosis of Ischemic Optic Neuropathy. This condition is debilitating, chronic condition that makes it very difficult to see, and drastically reduces the quality of life. Due to this debilitating diagnosis, he had lost all vision in his right eye, suffered a right eye stroke, and lost all peripheral vision in left eye leaving him with limited tunnel vision in one eye only. Mr. Ackerman's diagnoses were not related as being related to Amiodarone until approximately January 2016.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing Ischemic Optic Neuropathy, he was a remarkably healthy and active individual. He enjoyed regular exercise, weight lifting, swimming, biking, working in landscaping, being outdoors, and spending quality time with his family. After developing Optic Neuropathy, he now struggles with daily life functions due to his visual impairment. He is unable to enjoy the activities he once loved due to his vision loss.

j) Additionally, Plaintiff, Genieve Ackerman is the spouse of the Plaintiff Henry Ackerman, and resides with her spouse, and she depended on Henry Ackerman to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Henry Ackerman, Plaintiff Genieve Ackerman has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

9. **Plaintiffs Donald Hackerson and Carolyn Hackerson**

a) Plaintiff Donald Hackerson (hereinafter "Plaintiff" or Hackerson") is an individual who resides in Shelby County, Illinois. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced lung toxicity, a life-threatening and debilitating condition. In or around August 2008, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary complications, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around August of 2013 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Thomas Cahill prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by one or more of Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Thomas Cahill was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva

and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately July 2015, he began to experience a decline in his lung function, difficulty breathing, shortness of breath, fatigue, weakness and severe trouble walking. After several hospital admissions and treatment for pneumonia, atrial fibrillation, and pulmonary hypertension, he was presented with a diagnosis of Amiodarone-induced pulmonary complications. Pulmonary lung complications are debilitating, chronic condition that makes it very difficult to breathe, and drastically reduces the quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary complications, he was a remarkably healthy and active individual. He enjoyed going for walks, being outdoors,

and spending quality time with his wife and family members. After developing Amiodarone-induced pulmonary complications, he could not breathe without full time use of oxygen. He is now extremely limited with his ability to walk, and his quality of life has been reduced. As a result he also suffers from a litany of other health problems allegedly related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary complications.

j) Additionally, Plaintiff, Carolyn Hackerson is the spouse of the Plaintiff Donald Hackerson, and resides with her spouse, and she depended on Donald Hackerson to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Donald Hackerson, Plaintiff Carolyn Hackerson has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

10. **Plaintiffs James Walz and Mary Beth Walz**

a) Plaintiff James Walz (hereinafter "Plaintiff" or "Walz") is an individual who resides in Brevard County, Florida. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In June 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In June 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Matthew Campbell prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Campbell was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva

and potentially other manufacturers and distributors by McKesson to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2016, he began to experience shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. He was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual who enjoyed activities with his family, including dancing. After developing pulmonary fibrosis, he now struggles to exert himself as he used to. He also suffers from a litany of other health problems allegedly related to his use of Amiodarone and medications used to treat his pulmonary fibrosis.

j) Additionally, Plaintiff Mary Beth Walz is the spouse of the Plaintiff James Walz, and resides with her spouse, and she depended on Mr. Walz to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff James Walz, Plaintiff Mary Beth Walz has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for her.

11. **Plaintiff Judith Cote**

a) Plaintiff, Judith Cote (hereinafter "Plaintiff" or "Cote") is an individual who resides in Charleston County, South Carolina. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating condition. In approximately June 2003, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, she developed pulmonary toxicity, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In June 2003, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Telfair Parker prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Telfair Parker was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were

not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) In February 2016, she was admitted to the Medical University of South Carolina with worsening hypoxemia, dizziness and her oxygen saturations were worsening. She was given a diagnosis of interstitial lung disease and had a presumptive diagnosis of Amiodarone-induced pulmonary toxicity. She was ultimately diagnosed with pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly. She was told to stop taking Amiodarone in February 2016.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, she was a remarkably healthy and active individual. She spent a great deal of time with family and friends and enjoyed doing chores around the home. Only a few months later, after developing pulmonary fibrosis, she could not walk without the aid of a rolling walker or cane without being short of breath, coughing and increased heart rate, and is on oxygen twenty-four hours a day. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

12. **Plaintiff Theodore Almond**

a) On personal knowledge, Plaintiff Theodore Almond (hereinafter “Plaintiff” or “Almond”) is an individual who resides in Raleigh County, West Virginia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around December 2004, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE

TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In December 2004, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Anthony A. McFarlane prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by the Brand and/or Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Anthony McFarlane was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required

labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2012, he began to experience shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, difficulty sleeping, irritability, restlessness, decreased concentration, and depression. He was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, he was an active individual who enjoyed spending time with his family. After developing pulmonary fibrosis, he could not walk across the room and could barely exert himself. He also suffers from a litany of other health problems including hypothyroidism, vision loss, skin irritation and itching, and weight loss related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j) In or about May 2016, he discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary fibrosis, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his injuries. The Facebook page in question was a legal advertising page created by attorneys who had recently began litigation on behalf of Amiodarone users and was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

13. **Plaintiff Edward J. Miller, Jr.**

a) On personal knowledge, Plaintiff Edward J. Miller, Jr. (hereinafter “Plaintiff” or “Miller”) is an individual who resides in Rowan County, North Carolina. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition, as well as thyroid disease. In or around September 2009, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced hyperthyroid disease and decreased lung function, both serious and potentially deadly lung diseases. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a

prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Wyeth Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In September 2009, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Kruse prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Kruse was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the

Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2013, he began to experience shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. He was presented with a diagnosis of both Amiodarone-induced hyperthyroid disease and decreased lung function. These conditions are debilitating chronic, progressive conditions that only worsen over time. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced hyperthyroid disease and decreased lung function, he was a remarkably healthy and active individual. After he developed these complications, he required several hospitalizations and surgery to

remove his thyroid due to extreme complications related to his Amiodarone-induced hyperthyroid disease. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced hyperthyroid and lung disease.

j) In or about August 2016, he discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary fibrosis, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his injuries. The Facebook page in question was a legal advertising page created by attorneys who had recently began litigation on behalf of Amiodarone users and was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

14. **Plaintiff Thomas Hepler**

a) On personal knowledge, Plaintiff Thomas Hepler (hereinafter “Plaintiff” or “Hepler”) is an individual who resides in Nassau County, Florida. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around January 2015, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In January 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Arne Sippens prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Arne Sippens was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva

and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2015, he began to experience shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. He was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he requires oxygen, and he cannot walk without assistance. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis including anemia, excessive bleeding, and oxygen dependence.

15. **Plaintiffs Barbara King and Samuel King**

a) On personal knowledge, Plaintiff Barbara King (hereinafter “Plaintiff” or “King”) is an individual who resides in Richland County, South Carolina. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around September 2013, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She

consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In September 2013 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Hendricks prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Hendricks was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately June 2016, she began to experience shortness of breath, wheezing, trouble breathing, coughing, tiredness, vision deterioration, weakness, nervousness, edema, oxygen dependence, and abnormal thyroid function. She was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, she was a remarkably healthy and active individual. After developing pulmonary fibrosis, she could not walk across the room, and now requires constant dependence on oxygen. She also lost weight and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis, including an abnormal thyroid and vision problems.

j) Additionally, Plaintiff, Samuel King, is the spouse of the Plaintiff Barbara King, and resides with his spouse, and he depended on Barbara King to be his primary

caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Barbara King, Plaintiff Samuel King has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for her, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

16. **Plaintiffs Rickey A. Thomas and Carolyn Thomas**

a) On personal knowledge, Plaintiff Rickey A. Thomas (hereinafter "Plaintiff" or "Thomas") is an individual who resides in Chilton County, Alabama. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around December 2012, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He

consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In October 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Clifton Vance prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Clifton Vance was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately November 2014, he began to experience shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. He was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j) In or about May 2016, he discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary fibrosis, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought

legal representation regarding his injuries. The Facebook page in question was a legal advertising page created by attorneys who had recently began litigation on behalf of Amiodarone users and was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

k) Additionally, Plaintiff, Carolyn Thomas, is the spouse of the Plaintiff Rickey A. Thomas, and resides with her spouse, and she depended on Rickey Thomas to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Rickey Thomas, Plaintiff Carolyn Thomas has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

17. **Plaintiffs John Ackerman and Kim Ackerman**

a) On personal knowledge, Plaintiff John Ackerman (hereinafter "Plaintiff" or Ackerman") is an individual who resides in Milwaukee County, Wisconsin. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced lung toxicity, a life-threatening and debilitating condition. In or around December 2009, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed pulmonary toxicity, a serious and potentially deadly complication. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In or around December 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Charles Lanzarotti prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Charles Lanzarotti was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication

Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately October 2011, he began to experience a decline in his lung function, difficulty breathing, shortness of breath, fatigue, weakness and irregular heart rate and depression. After several medical evaluations and treatments for atrial fibrillation, he was subsequently presented with a diagnosis of pulmonary toxicity. Pulmonary toxicity is a debilitating, chronic condition that makes it very difficult to breathe, and drastically reduces the quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary complications, he was a remarkably healthy and active individual. He enjoyed being active, being outdoors, and

spending quality time with his wife and family members. After developing Amiodarone-induced pulmonary toxicity, he could not breathe without wheezing and difficulty. He is now extremely limited and his quality of life has been reduced. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j) In or about June 2016, he discovered a Facebook page discussing the serious complications of Amiodarone, including lung toxicity, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his injuries. The Facebook page in question was a legal advertising page created by attorneys who had recently began litigation on behalf of Amiodarone users and was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

k) Additionally, Plaintiff Kim Ackerman is the spouse of the Plaintiff John Ackerman, and resides with her spouse, and she depended on John Ackerman to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff John Ackerman, Plaintiff Kim Ackerman has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

18. **Plaintiffs Albert Delsantro and Charlotte Delsantro**

a) On personal knowledge, Plaintiff Albert Delsantro (hereinafter "Plaintiff" or "Delsantro") is an individual who resides in Lackawanna County, Pennsylvania. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around

June 2013, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around September 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Matthew Stopper prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Matthew Stopper was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation,

which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2014, he began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, kidney damage, abnormal hemorrhaging, chest pain, dizziness, and depression. He was subsequently presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year

survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room or exercise as he did prior to his Amiodarone use. His medical complications resulted in numerous hospitalizations and a significant decline in his quality of life. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis including COPD, kidney damage, cardiomyopathy, CHF and hypertension.

j) In or about June 2016, he discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary fibrosis, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his injuries. The Facebook page in question was a legal advertising page created by attorneys who had recently began litigation on behalf of Amiodarone users and was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

k) Additionally, Plaintiff Charlotte Delsantro is the spouse of the Plaintiff Albert Delsantro, and resides with her spouse, and she depended on Albert Delsantro to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Albert Delsantro, Plaintiff Charlotte Delsantro has in the past and will in the future suffer and incur loss of his consortium, loss of her

spouse's services, the cost and expense of having medical care, attention and treatment for his/her, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

19. **Plaintiff Richard Bresette**

a) On personal knowledge, Plaintiff Richard Bresette (hereinafter "Plaintiff" or "Bresette") is an individual who resides in Santa Rosa County, Florida. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and vision deterioration, as well as kidney damage, both which are life-altering and debilitating conditions. In or around December 2015, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss and deterioration as well as kidney damage. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for "off-label" use by them.

d) In February 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Jerry Leventhal prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jerry Leventhal was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-

threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately June 2016, he began to experience kidney damage, hypothyroidism, vision loss including macular degeneration, weight loss, edema, difficulty sleeping, shortness of breath, coughing, skin rashes, fatigue, weakness, irritability, restlessness, and chest pain. He was presented with a diagnosis of Amiodarone-induced kidney damage and vision loss including macular degeneration. These debilitating and irreversible diagnoses do not improve over time and drastically altered his quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced kidney damage and vision loss, he was a healthy and active individual. The complications related to his Amiodarone use has had a major impact on his quality of life and has reduced his ability to engage and enjoy in things he once loved. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced complications, including pulmonary hypertension, hypothyroidism, anemia, and abnormal liver function tests.

20. **Plaintiff Ralph L. Booth**

a) On personal knowledge, Plaintiff, Ralph Booth (hereinafter "Plaintiff" or "Booth") is an individual who resides in Suffolk County, Virginia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more

fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced lung disease, a life-threatening and debilitating condition. In December, 2013, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In December 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Bhavdeep Gupta prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Bhavdeep Gupta was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as

continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2016, he began to experience shortness of breath, coughing, exhaustion and overall weakness. He went to the hospital and a high definition CT scan was performed. The CT scan confirmed he had severe

lung damage and Amiodarone toxicity. He was also diagnosed with anemia with renal failure. His severe lung condition worsened and even on oxygen he was still unable to breathe easily. His cardiologist stopped his Amiodarone and began a course of treatment of prednisone and bactrim.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone toxicity and renal failure, he was a remarkably healthy and active individual. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced lung disease.

21. **Plaintiffs Hans Omasta and Winona Omasta**

a) On personal knowledge, Plaintiff, Hans Omasta (hereinafter "Plaintiff" or "Omasta") is an individual who resides in Gilmer County, Georgia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and impairment, a life-altering and debilitating condition. In August 2008, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, he developed Amiodarone-induced vision loss and impairment. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the

FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In August 2008, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Jimmie Dale Cannon prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jimmie Dale Cannon was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with

his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately September 2016, he began to experience impaired vision, spots before his eyes and headaches. His optometrist diagnosed the retina deposit scars and vision loss as related to Amiodarone use and recommended that his cardiologist stop prescribing Amiodarone. The Amiodarone treatment was stopped.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing retinal deposit scars, also referred to as Amiodarone deposits, he was a remarkably healthy and active individual. He now cannot enjoy reading, watching television and everyday activities. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced vision loss.

j) Additionally, Plaintiff Winona Omasta is the spouse of the Plaintiff Hans Omasta and resides with her spouse, and she depended on Plaintiff Hans Omasta to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Hans Omasta, Plaintiff Winona Omasta has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

22. **Plaintiffs Eddie W. Bates and Linda Bates**

a) On personal knowledge, Plaintiff, Eddie W. Bates (hereinafter "Plaintiff" or "Bates") is an individual who resides in Tulsa County, Oklahoma. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and impairment, a life-altering and debilitating condition. In September 2013, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss and impairment. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In September 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. James Loman prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. James Loman was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required

labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately March 2016, he began to experience impaired vision, spots before his eyes, dizziness, faintness and headaches. It was determined that the vision loss was caused by the use of Amiodarone. The Amiodarone treatment was stopped.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing vision impairment, also referred to as Amiodarone deposits, he was a remarkably healthy and active individual. He now cannot enjoy reading, watching television and everyday activities. He also suffers from red skin and face, extreme fatigue, an overall weakness and a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced vision loss.

j) Additionally, Plaintiff Linda Bates is the spouse of the Plaintiff Eddie Bates and resides with her spouse, and she depended on Plaintiff Eddie Bates to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Eddie Bates, Plaintiff, Linda Bates has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's

services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

23. **Plaintiff Charles D. Smedley**

a) On personal knowledge, Plaintiff Charles D. Smedley (hereinafter “Plaintiff” or “Smedley”) is an individual who resides in Fulton County, Georgia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around December 2015, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In December 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Kim Champney prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Champney was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-

threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately February 2016, he began to experience shortness of breath, trouble breathing, coughing, fatigue, weakness, weight loss, difficulty walking, and abnormal bleeding. He was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. He enjoyed spending time with his family, working and walking dogs. After developing pulmonary fibrosis, he could not walk or exert himself without significant difficulty. His breathing had become so difficult he quickly became oxygen dependent. His Amiodarone-induced complications have significantly decreased his quality of life. As his condition deteriorated, he spent a significant amount of time in the hospital.

24. **Plaintiff Marchette Cook**

a) On personal knowledge, Marchette Cook, individually and as Personal Representative of the Estate of Alice Southerland, deceased (hereinafter "Plaintiff" or "Southerland") is an individual who resides in New Castle County, Delaware. Ms.

Southerland was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease and respiratory failure, as well as liver injury, all of which are life-threatening and debilitating conditions. In January 2014, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease and liver injury, both serious and potentially deadly diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them,.

d) In or around January 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. James Hopkins and Dr. Susan Chudzik prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. These prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She

filled the prescription and ingested the drug Amiodarone as prescribed. Dr. James Hopkins and Dr. Susan Chudzik were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of

the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately October 2014, she began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, dizziness, weakness, hepatic enlargement and cysts, and pulmonary edema. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease which led up to respiratory failure. Interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. This lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly. In addition to interstitial lung disease, she also developed liver injury including hepatic cysts and enlargement.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced interstitial lung disease and liver injury, Plaintiff was a remarkably healthy and active individual. After developing pulmonary and liver damage, she was often short of breath, dizzy, and suffered from several pneumonias. She also lost weight and suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced interstitial lung disease and liver injury.

j) After developing Amiodarone-induced interstitial lung disease, she developed pneumonia and her condition deteriorated rapidly, requiring hospitalization. She could not adequately breathe on her own and suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced complications. After spending more than a week in the hospital,

Alice Southerland succumbed to her Amiodarone-induced respiratory failure on November 24, 2014.

k) At some point in 2016, Mr. Marchette discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary toxicity, and the fact it was not FDA-approved for treatment of atrial fibrillation. Thereafter, he sought legal representation regarding his wife's injuries. The Facebook page in question was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries Ms. Sutherland suffered were caused by wrongdoing on the part of the Defendants.

25. **Plaintiff Ty Beard**

a) On personal knowledge, Plaintiff Ty Beard (hereinafter "Plaintiff" or "Beard") is an individual who resides in Travis County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision injury and loss, a life-altering and debilitating condition. In or around June 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision injury and loss, a serious and potentially disabling condition. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a

prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In July 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Samuel DeMaio prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Samuel DeMaio was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and

ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2016, he began to experience vision loss and partial blindness, total loss of peripheral vision, light sensitivity, poor coordination due to vision loss, shortness of breath on exertion and fatigue. He was presented with a diagnosis of Amiodarone-induced loss and partial blindness in both eyes. Amiodarone-induced vision loss is a debilitating condition that could worsen over time resulting in other visual complications including but not limited to eye pain, irritation, floaters, retinal detachment, corneal disease, optic neuropathy, cataracts, and Amiodarone deposits within the eye. Amiodarone-induced vision loss often cannot be corrected and results significant limitations and impairment on quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced vision loss and partial blindness, Plaintiff was a remarkably healthy and active individual. He enjoyed spending time with his family and working. After developing vision loss, he struggles to enjoy regular

activities such as reading, driving and watching television, and often requires assistance. He also and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat her Amiodarone-induced vision loss.

26. **Plaintiff Vernon DeBoard**

a) On personal knowledge, Vernon DeBoard, individually and as Personal Representative of the Estate of Katherine DeBoard, deceased (hereinafter “Plaintiff” or “DeBoard”) is an individual who resides in Butler County, Ohio. Mrs. DeBoard was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced liver toxicity, renal failure and pancreatitis, all life-threatening and debilitating conditions. In June 2013, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced liver toxicity, renal failure and pancreatitis, all serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. M. Atia Khalid prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. M. Atia Khalid was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription, insufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-

threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2015, she began to experience shortness of breath, abdominal pain, weakness, difficulty with exertion, abnormal kidney function, liver toxicity, and abnormal pancreas function. She was presented with a diagnosis of Amiodarone-induced liver toxicity, acute renal failure and acute pancreatitis. These life-threatening injuries are debilitating chronic, progressive conditions that only worsen over time. The five-year survival rate for individuals with organ toxicity is extremely poor.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing liver toxicity, renal failure and pancreatitis, Plaintiff was a healthy and active individual. After developing these multi-organ injuries, she could not walk across the room and was frequently hospitalized. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat his Amiodarone-induced injuries.

j) At some point in 2016, Mr. DeBoard discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary toxicity, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his wife's injuries. The Facebook page in question was not published until 2015. It was not until he learned of these facts

that he knew, or reasonably should have known, that the injuries his wife suffered were caused by wrongdoing on the part of the Defendants.

k) After developing Amiodarone-induced liver toxicity, renal failure, and pancreatitis, her condition deteriorated rapidly, requiring hospitalization. Her condition worsened, requiring a significant amount of time in the hospital. Katherine DeBoard succumbed to her Amiodarone-induced liver toxicity, renal failure and pancreatitis on February 11, 2015.

27. **Plaintiffs John Davis, Jr. and Deborah Davis**

a) On personal knowledge, Plaintiff John Davis, Jr. (hereinafter “Plaintiff” or “Davis”) is an individual who resides in Madison County, Georgia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating condition. In or around June 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease, a serious and potentially deadly lung disease, as well as vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In June 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. L. Steven Lowman prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. L. Steven Lowman was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required

labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately September 2015, he began to experience shortness of breath, wheezing, difficulty breathing, coughing, fatigue, weakness, anxiety, abnormal liver function and abnormal kidney function. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) At some point in 2016, Plaintiff discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary toxicity, and the fact it was not FDA-approved for treatment of atrial fibrillation. Thereafter, he sought legal representation regarding his injuries. The Facebook page in question was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

i) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and

sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

j) Before developing Amiodarone-induced pulmonary toxicity, Plaintiff was a remarkably healthy and active individual. After developing pulmonary toxicity he developed frequent pneumonia requiring regular use of oxygen, making it difficult to exert himself. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity, including kidney disease and abnormal liver function.

k) Additionally, Plaintiff Deborah Davis is the spouse of the Plaintiff John Davis, Jr., and resides with her spouse, and she depended on John Davis, Jr. to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff John Davis, Jr., Plaintiff Deborah Davis has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

28. **Plaintiffs Kenneth Collins and Kim Collins**

a) On personal knowledge, Plaintiff Kenneth Collins (hereinafter "Plaintiff" or "Collins") is an individual who resides in Knox County, Tennessee. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury and vision loss, life-threatening and debilitating conditions. In or around April 2013, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease, a serious and potentially deadly lung disease, as well as vision loss. He received

no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In January 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Kyle McCoy prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Kyle McCoy was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his

prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately June 2016, he began to experience shortness of breath, wheezing, trouble breathing, fatigue, chest pain, weakness, blurred vision and vision loss, skin rashes, dizziness and numbness. He was presented with a diagnosis of Amiodarone-induced pulmonary disease and vision loss. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution and

sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary disease and vision loss, Plaintiff was a remarkably healthy and active individual. After developing pulmonary injury and vision loss, he struggles to exert himself and to enjoy the things he once did. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary injury.

j) Additionally, Plaintiff Kim Collins is the spouse of the Plaintiff Kenneth Collins, and resides with her spouse, and she depended on Kenneth Collins to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Kenneth Collins, Plaintiff Kim Collins has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

29. **Plaintiff Carolyn Harrison**

a) On personal knowledge, Carolyn Harrison, Individually and as Personal Representative of the Estate of Gerald Harrison, deceased (hereinafter "Plaintiff" or "Harrison") is an individual who resides in Prince George County, Virginia. Mr. Harrison was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In April 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician

about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around April 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Mesele Gebreyes prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mesele Gebreyes was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his

prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately August 2015, he began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, vision loss, edema, anxiety and depression. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution and

sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room and suffered frequent pneumonias. He also lost suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis including congestive heart failure and vision loss.

j) After developing pulmonary fibrosis his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After spending 15 days in the hospital, Gerald Harrison succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on October 11, 2015.

30. **Plaintiffs Kay Ann Rice and Robert Rice**

a) On personal knowledge, Plaintiff Kay Ann Rice (hereinafter “Plaintiff” or “Rice”) is an individual who resides in Lucas County, Ohio. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease and vision loss, life-threatening and debilitating conditions. In July 2014, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In October 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Laura Murphy prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Laura Murphy was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were

not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2016, she began to experience shortness of breath, difficulty breathing, coughing, vision loss, edema, fatigue, weakness, abdominal pain and respiratory failure. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease, respiratory failure and vision loss. Interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing interstitial lung disease and vision loss, Plaintiff was a remarkably healthy and active individual. After developing interstitial lung disease and respiratory failure she could not walk across the room and is now oxygen dependent. She struggles with vision loss and deterioration making it difficult to perform her daily life activities. In addition, she also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary injuries.

j) Additionally, Plaintiff Robert Rice is the spouse of the Plaintiff Kay Ann Rice, and resides with his spouse, and he depended on Kay Ann Rice to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Kay Ann Rice, Plaintiff Robert Rice has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

31. **Plaintiff Lois Roncal**

a) On personal knowledge, Plaintiff Lois Roncal (hereinafter "Plaintiff" or "Roncal") is an individual who resides in Smith County, Texas. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision injury and loss, a life-altering and debilitating condition. In or around April 2015, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced vision injury and loss, a serious and potentially disabling condition. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had

not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In April 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Roderick Meese prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Roderick Meese was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by

Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2015, she began to experience vision loss, eye pain, floaters, loss of visual acuity, trouble with coordination due to vision loss, corneal damage and ulcers, trouble breathing, coughing, and fatigue. She was presented with a diagnosis of Amiodarone vision injury and loss including corneal ulcers and damage. In addition, she suffered pulmonary injury and difficulty breathing because of her Amiodarone use. Amiodarone-induced vision loss is a debilitating condition that could worsen over time resulting in other visual complications. Amiodarone-induced vision loss injury and loss often cannot be corrected and causes a significant impairment on quality of life.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these

diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing vision injury and loss and pulmonary complications, Plaintiff was a remarkably healthy and active individual. After developing these injuries, she could not easily read or drive and she was often fatigued and short of breath. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced vision injury and pulmonary injury.

32. **Plaintiff Darlene Heronema**

a) On personal knowledge, Plaintiff Darlene Heronema (hereinafter "Plaintiff" or "Heronema") is an individual who resides in Jefferson County, Colorado. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury and vision loss, a life-threatening and debilitating condition. In March 2015, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary injury and vision loss, a serious and potentially disabling condition. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In March 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Michael Wahl and Dr. Michael Ptsnik prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Michael Wahl and Dr. Michael Ptsnik were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required

labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately November 2015, she began to experience shortness of breath, difficulty with exertion, coughing, fatigue, weakness, weight gain, palpitations, vision loss, and abnormal liver function. She was presented with a diagnosis of Amiodarone-induced pulmonary injury and vision loss. Amiodarone-induced pulmonary injury is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary injury is extremely poor. Amiodarone-induced pulmonary injury causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary injury and vision loss, Plaintiff was a healthy and active individual. After developing these injuries, she struggled to exert herself and was often short of breath. She also gained weight and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary injury, including abnormal liver function and vision loss.

33. **Plaintiffs Katherine Wollaston and Daniel Wollaston**

a) On personal knowledge, Plaintiff Katherine Wollaston (hereinafter “Plaintiff” or “Wollaston”) is an individual who resides in Chautauqua County, New York. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury and kidney disease, life-threatening and debilitating conditions. In or around April 2003, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary injury and kidney disease, both serious and potentially deadly diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around October 2003, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Jeffrey

Dakas and Dr. Kelly Hayes prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jeffrey Dakas and Dr. Kelly Hayes were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was

not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately April 2015, she began to experience shortness of breath, wheezing, trouble with exertion, coughing, fatigue, kidney disease, weakness, weight fluctuations, increased anxiety, and oxygen dependence. She was presented with a diagnosis of kidney disease and pulmonary injury including pulmonary hypertension, and restrictive lung disease. Pulmonary injury and pulmonary hypertension are debilitating chronic, progressive conditions that only worsen over time. The survival rate for individuals with Amiodarone-induced pulmonary injury, pulmonary hypertension and kidney disease is extremely poor. Restrictive pulmonary disease and pulmonary hypertension cause the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing her Amiodarone-induced pulmonary and kidney injuries, Plaintiff was a remarkably healthy and active individual. After developing restrictive pulmonary injury and pulmonary hypertension, she struggles to walk across the room and breathe comfortably. Her lung injuries have caused her to be oxygen dependent and she relies on the use of a BiPap and CPAP machine to assist in her breathing. She also suffers weight fluctuations and has significant difficulty sleeping due to her kidney and lung disease. She suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced restrictive pulmonary disease.

j) In or about May 2016, Plaintiff discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary injury and kidney injury, and

the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, she sought legal representation regarding her injuries. The Facebook page in question was not published until 2015. It was not until she learned of these facts that she knew, or reasonably should have known, that the injuries she suffered were caused by wrongdoing on the part of the Defendants.

k) Additionally, Plaintiff Daniel Wollaston is the spouse of the Plaintiff Katherine Wollaston, and resides with his spouse, and he depended on Katherine Wollaston to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Katherine Wollaston, Plaintiff Daniel Wollaston has in the past and will in the future suffer and incur loss of his consortium, loss of his spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

34. **Plaintiffs George Chosich and Elizabeth Chosich**

a) On personal knowledge, Plaintiff George Chosich (hereinafter "Plaintiff" or "Chosich") is an individual who resides in Ocean County, New Jersey. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and injury, a life-altering and debilitating condition. In or around December 2002, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss/injury, a serious and potentially disabling condition. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In December 2002, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Leonard DiPisa prescribed Plaintiff a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Leonard DiPisa was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and

potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately 2014, he began to experience vision loss, dizziness, unequal pupils, loss of visual acuity, tremors, and poor coordination due to vision loss, and trouble breathing. He was presented with a diagnosis of Amiodarone-induced vision loss and injury in both eyes. Amiodarone-induced vision loss is a debilitating condition that could worsen over time resulting in other visual complications including but not limited to, eye pain, irritation, floaters, retinal detachment, corneal disease, optic neuropathy, loss of visual acuity and peripheral vision, deposits within the eye, and cataracts. Amiodarone-induced vision loss/injury often cannot be corrected and causes a significant impairment on quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing vision loss and injury, Plaintiff was a remarkably healthy and active individual. After developing vision loss and injury, he could not easily read or drive. He also and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced vision loss/injury.

j) In or about April 2016, his family discovered a Facebook page discussing the serious complications of Amiodarone, including vision loss/injury, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his injuries. The Facebook page in question was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

k) Additionally, Plaintiff Elizabeth Chosich is the spouse of Plaintiff George Chosich, and resides with her spouse, and she depended on George Chosich to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff George Chosich, Plaintiff Elizabeth Chosich has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

35. **Plaintiff Peggy Brown**

a) On personal knowledge, Plaintiff Peggy Brown (hereinafter "Plaintiff" or "Brown") is an individual who resides in Troup County, Georgia. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss/injury, a life-altering and debilitating condition. In approximately June 2014, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial

chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced vision loss and injury, a serious and potentially disabling condition. She received no warning from her physician about these potential life-altering complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. James Brennen prescribed Plaintiff a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. James Brennen was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2015, she began to experience vision loss related to deposits within her eyes, floaters, glaucoma, trouble with coordination due to vision loss, dizziness, and migraines. She was presented with a diagnosis of Amiodarone-induced vision loss. Amiodarone-induced vision loss is a debilitating condition that could worsen over time resulting in other visual complications, including, but not limited to, eye pain, irritation, floaters, retinal detachment, corneal

disease, optic neuropathy, loss of visual acuity and peripheral vision, deposits within the eye, and cataracts. Amiodarone-induced vision loss/injury often cannot be corrected and results in significant impairment on the quality of life.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing vision loss/injury, Plaintiff was a remarkably healthy and active individual. After developing vision loss, she could not easily read, watch television or drive. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced vision loss/injury.

36. **Plaintiff Mary Ann Minasian**

a) On personal knowledge, Plaintiff Mary Ann Minasian (hereinafter "Plaintiff" or "Minasian") is an individual who resides in Greene County, Ohio. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around October 2013, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In October 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Marcus Williams prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Marcus Williams was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not

provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately May 2015, she began to experience shortness of breath, wheezing, difficulty breathing, coughing, fatigue, weakness, abnormal thyroid function, and chest pains. She was subsequently presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, she could not walk across the room and required oxygen to breathe. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis including congestive heart failure and pulmonary hypertension.

j) In or about September 2016, Plaintiff discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary fibrosis, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, she sought legal representation regarding her injuries. The Facebook page in question was not published until 2015. It was not until she learned of these facts that she knew, or reasonably should have known, that the injuries she suffered were caused by wrongdoing on the part of the Defendants.

37. **Plaintiff Lee Alvin Smith**

a) On personal knowledge, Plaintiff Lee Alvin Smith (hereinafter “Plaintiff” or “Smith”) is an individual who resides in Leavenworth County, Kansas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed multiple Amiodarone-induced vision injuries and vision loss, a life-altering and debilitating condition. In January 2012, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss/injury, a serious and potentially disabling condition. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In January 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Christos Mandanis prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Chistos Mandanis was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and

potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately September 2013, he began to experience vision loss, floaters, loss of visual acuity, eye pain, dizziness, nausea and trouble with coordination due to vision loss. He was presented with a diagnosis of ischemic optic atrophy, cataracts, macular degeneration and optic nerve damage in the left eye. These Amiodarone-induced vision injuries are debilitating conditions that often worsen over time resulting in other visual complications. Amiodarone-induced vision loss/injury often cannot be corrected and cause significant impairment on the quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing multiple Amiodarone-induced vision injuries, Plaintiff was a remarkably healthy and active individual. After developing vision loss and injury,

he could not easily read or drive. His vision injuries significantly impaired his quality of life. His injuries required him to undergo eye surgery and numerous evaluations for these conditions. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced vision loss/injury.

j) In or about April 2016, his family discovered a Facebook page, discussing the serious complications of Amiodarone, including vision loss/injury, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his injuries. The Facebook page in question was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

38. **Plaintiff Mary Parker**

a) On personal knowledge, Plaintiff Mary Parker (hereinafter “Plaintiff” or “Parker”) is an individual who resides in Rutherford County, Indiana. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In April 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she

receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around April 2011, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Aravind Reddy prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Aravind Reddy was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not

receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately April 2016, she began to experience shortness of breath, wheezing, edema, coughing, fatigue, and weakness. She was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, she struggled to walk or exert herself. She became dependent on oxygen to breathe adequately. Due to her Amiodarone-induced pulmonary fibrosis, she became more susceptible to developing frequent pneumonias resulting in frequent hospitalizations and treatment. She also suffers

from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis including cardiomegaly, and pulmonary hypertension.

j) In or about June 2016, Plaintiff discovered a Facebook page, discussing the serious complications of Amiodarone, including pulmonary fibrosis, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, she sought legal representation regarding her injuries. The Facebook page in question was not published until 2015. It was not until she learned of these facts that she knew, or reasonably should have known, that the injuries she suffered were caused by wrongdoing on the part of the Defendants.

39. **Plaintiff Brian Sukenik**

a) On personal knowledge, Plaintiff Brian Sukenik (hereinafter “Plaintiff” or “Sukenik”) is an individual who resides in Cambria County, Pennsylvania. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating condition. In March 2014, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a

prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In April 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Cyril Nathaniel prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Cyril Nathaniel was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a

mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately October 2015, he began to experience shortness of breath, wheezing, dizziness, chest pain, skin lesions/growths, memory loss, abnormal bleeding and bruising, edema, coughing, fatigue, weakness, and increased anxiety. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary toxicity, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, he struggled to exert himself, required a CPAP machine for breathing assistance, and both his liver and kidney function declined. He also suffers from a litany

of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity including congestive heart failure, anemia, skin lesions/growths, abnormal liver function and kidney disease.

j) In or about April 2016, Plaintiff discovered a Facebook page, discussing the serious complications of Amiodarone, including pulmonary toxicity, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his injuries. The Facebook page in question was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

40. **Plaintiff Linda Brunner**

a) On personal knowledge, Plaintiff Linda Brunner (hereinafter “Plaintiff” or “Brunner”) is an individual who resides in Butler County, Ohio. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss/injury, a life-altering and debilitating condition. In or around June 2015, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced vision loss and injury, a serious and potentially disabling condition. She received no warning from her physician about these potential debilitating complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a

prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. George S. George prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. George S. George was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received

and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately April 2016, she began to experience vision loss and difficulty seeing as a result of the Amiodarone-induced corneal deposits within her eyes, trouble with coordination due to vision loss, floaters, decreased visual acuity, and increased anxiety. She was presented with a diagnosis of Amiodarone-induced epithelial corneal deposits, astigmatism and presbyopia. Amiodarone-induced vision injury is debilitating and is known to worsen over time and may result in other visual complications including but not limited to, eye pain, irritation, floaters, corneal disease, loss of visual acuity and peripheral vision, deposits within the eye, and cataracts.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing vision injury, Plaintiff was a remarkably healthy and active individual. After developing vision injury, she could not easily read or drive or

continue working. Amiodarone-induced vision injury and vision loss has resulted in significant impairment on her quality of life.

j) In or about May, 2016, her family discovered a Facebook page, discussing the serious complications of Amiodarone, including vision loss/injury, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, she sought legal representation regarding her injuries. The Facebook page in question was not published until 2015. It was not until she learned of these facts that she knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

41. **Plaintiff Dennis Workman**

a) On personal knowledge, Plaintiff Dennis Workman (hereinafter “Plaintiff” or “Workman”) is an individual who resides in Wood County, West Virginia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury, thyroid disease and abnormal liver function, all life-threatening and debilitating conditions. In or around May 2012, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary injury, a serious and potentially deadly lung disease. In addition to his pulmonary injury, he also suffered hypothyroid disease and abnormal liver function related to his Amiodarone use. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he

receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In May 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Stanley Pamfilis prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Stanley Pamfilis was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication

Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately May 2014, he began to experience shortness of breath, chest pain, trouble breathing, coughing, fatigue, weakness, abnormal liver enzymes, memory loss, fainting, and significant weight fluctuations. He was presented with a diagnosis of pulmonary injury including pulmonary hypertension. Amiodarone-induced pulmonary injury and pulmonary hypertension are debilitating chronic, progressive conditions that only worsen over time. The survival rate for individuals with Amiodarone-induced pulmonary injury is extremely poor. Amiodarone-induced pulmonary injury and pulmonary hypertension causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly. In addition to pulmonary injuries, he also suffered abnormal liver enzymes and function as well as hypothyroidism.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing pulmonary injury and pulmonary hypertension, Plaintiff was a remarkably healthy and active individual. After developing pulmonary injuries, abnormal liver function and thyroid disease, he struggled to perform regular daily life activities, he was chronically fatigued and weak, and often required assistance for his personal needs. He also lost and gained weight frequently and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary injuries.

j) In or about August 2016, Plaintiff discovered a Facebook page, discussing the serious complications of Amiodarone, including pulmonary injury, liver malfunction and thyroid disease, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his injuries. The Facebook page in question was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

42. **Plaintiff Mary Waters**

a) On personal knowledge, Plaintiff Mary Waters (hereinafter “Plaintiff” or “Waters”) is an individual who resides in Beaufort County, North Carolina. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease, a life-threatening and debilitating condition. In or around August 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly pulmonary disease. In addition to lung disease, she also suffered vision injuries, including glaucoma and cataracts. She received no warning from her physician about these potential life-threatening complications, nor did

any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In June 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Jerry Simpson prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jerry Simpson was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not

receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2015, she began to experience shortness of breath, trouble breathing, coughing, fatigue, weakness, vision loss and injury including cataracts and glaucoma, and difficulty with exertion. She was presented with a diagnosis of interstitial lung disease. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly. She also suffered vision impairment due to her Amiodarone-induced cataracts and glaucoma, making it difficult to see clearly as she once did.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these

diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing interstitial lung disease, Plaintiff was a remarkably healthy and active individual. After developing interstitial lung disease and vision loss, she struggled to perform regular life activities such as exercise, walking, and reading. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone induced interstitial lung disease and vision impairment.

j) In or about May, 2016, her family discovered a Facebook page, discussing the serious complications of Amiodarone, including interstitial lung disease, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, she sought legal representation regarding her injuries. The Facebook page in question was not published until 2015. It was not until she learned of these facts that she knew, or reasonably should have known, that the injuries she suffered were caused by wrongdoing on the part of the Defendants.

43. **Plaintiffs George Schmidt and Sharon Schmidt**

a) On personal knowledge, Plaintiff George Schmidt (hereinafter "Plaintiff" or "Schmidt") is an individual who resides in Gordon County, Georgia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision injury and loss, a life-threatening and debilitating condition. In May 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced ischemic optic neuropathy, a serious and potentially disabling condition. He received no warning from his physician about

these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In or around March 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Styperek prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Styperek was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®,

Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately November 2015, he began to experience total vision loss in his right eye, blurry vision, floaters, loss of visual acuity, trouble with coordination due to vision loss, cataracts, fatigue and anxiety. He was presented with a diagnosis of Amiodarone-induced ischemic optic neuropathy, whorl keratopathy (amiodarone deposits within the eye), and cataracts resulting in total vision loss in his right eye. Amiodarone-induced vision loss is a debilitating condition that could worsen over time resulting in other visual complications and total blindness. Amiodarone-induced vision loss/injury often cannot be corrected and causes a significant impairment on quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing vision loss/injury, he was a remarkably healthy and active individual. After developing Amiodarone-induced vision loss and injury, he could not easily read, watch television or drive. He now requires assistance with daily life activities. He also and suffers from a litany of other health problems related to his use of amiodarone and medications used to treat his amiodarone induced vision loss/injury.

j) Additionally, Plaintiff, Sharon Schmidt, is the spouse of the Plaintiff George Schmidt, and resides with her spouse, and she depended on George Schmidt to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff George Schmidt, Plaintiff Sharon Schmidt has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

44. **Plaintiffs Clinton Humphrey and Tenna Humphrey**

a) On personal knowledge, Plaintiff Clinton Humphrey hereinafter "Plaintiff" or "Humphrey") is an individual who resides in Santa Rosa County, Florida. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced thyroid injury a life-threatening and debilitating condition. In or around January 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a

proximate result of his Amiodarone use, he developed Amiodarone-induced hyperthyroidism disease, a serious and potentially deadly lung disease, as well as vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around March 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Vardenra Panchamukhi, prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Vardenra Panchamukhi was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation.

Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately March 2015, he began to experience confusion, tremors, memory loss, fatigue, weakness, and poor coordination. He was presented with a diagnosis of amiodarone induced hyperthyroidism. Amiodarone induced hyperthyroidism is a debilitating chronic, progressive condition that may worsen over time resulting in further complications.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution and

sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing hyperthyroidism, he was a remarkably healthy and active individual. After developing amiodarone induced thyroid disease, he was often weak, confused and struggled to exert himself. He also suffers from a litany of other health problems related to his use of amiodarone and medications used to treat his amiodarone induced thyroid disease.

j) Additionally, Plaintiff, Tenna Humphrey, is the spouse of the Plaintiff Clinton Humphrey, and resides with her spouse, and she depended on Clinton Humphrey to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Clinton Humphrey, Plaintiff Tenna Humphrey has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

45. **Plaintiffs Betty Bostic and Jimmy Bostic**

a) On personal knowledge, Plaintiff Betty Bostic (hereinafter "Plaintiff" or "Bostic") is an individual who resides in Pulaski County, Arizona. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury, severe and debilitating vision condition. In approximately January 2013, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be amiodarone. As a proximate result of her amiodarone use, she developed amiodarone-induced pulmonary injury and vision loss, both serious and debilitating diseases. She received no warning from her physician about these potential life threatening complications, nor did any warnings that Amiodarone had

not been approved and was not an appropriate treatment for A-fib accompany the purchase of amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately January 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Hakan Paydak prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jeffrey Dell was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that his use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, she did not receive the

required Medication Guide for the prescriptions he filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately July 2015, she began to experience shortness of breath, wheezing, difficulty breathing, coughing, fatigue, weakness, vision loss, blurry vision, confusion, hair loss, weight fluctuations, anemia, and abnormal bleeding. She was presented with a diagnosis of amiodarone induced pulmonary disease and vision loss. Amiodarone induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with amiodarone induced pulmonary injury is extremely poor. Amiodarone pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture,

distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing amiodarone induced pulmonary disease and vision loss, Plaintiff was a remarkably healthy and active person who enjoyed spending time with her family. After developing amiodarone induced pulmonary disease and vision loss, she struggles to perform daily living tasks independently, and struggles exert herself, and she struggles to read, watch television, and drive. Her vision and pulmonary injuries have significantly impacted the quality of her life. She also gained weight and suffers from a litany of other health problems related to her use of amiodarone and medications used to treat her amiodarone induced pulmonary and vision injuries.

j) Additionally, Plaintiff Jimmy Bostic, is the spouse of the Plaintiff Betty Bostic, and resides with his spouse, and he depended on Betty Bostic to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Betty Bostic, Plaintiff Jimmy Bostic has in the past and will in the future suffer and incur loss of her consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

46. **Plaintiff Georgia Sutton**

a) On personal knowledge, Plaintiff Georgia Sutton (hereinafter "Plaintiff" or "Sutton") is an individual who resides in New Castle County, Delaware. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around June 2009, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate

result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2009, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth and other Defendants to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Paul Alfieiri and Dr. Kenneth Corrine prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Paul Alfieiri and Dr. Kenneth Corrine were victims of Wyeth’s long-term and successful promotional efforts as well as Teva and potentially other manufacturers’ marketing and sales efforts that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately June 2015, she began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain, fainting, edema, and irregular heart rate. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease. Interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease

causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing interstitial lung disease, she was a remarkably healthy and active individual. After developing interstitial lung disease, she struggled to exert herself and was often fatigued. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced vision injury and pulmonary injury.

47. **Plaintiff Braha Jackson**

a) On personal knowledge, Plaintiff Braha Jackson (hereinafter "Plaintiff" or "Jackson") is an individual who resides in Anderson County, Tennessee. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, a life-altering and debilitating condition. In or around February 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, she developed Amiodarone-induced pulmonary disease, a serious and potentially deadly lung injury. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately February 2011, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Sharma prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Sharma was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not

provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately November 2016, she began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, chest pain, weakness, dizziness and edema. She was presented with a diagnosis of Amiodarone-induced pulmonary disease and pulmonary edema. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary disease and pulmonary edema, Plaintiff was a remarkably healthy and active individual. After developing pulmonary disease and pulmonary edema, she struggles to exert herself and is often short of breath. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary injuries.

48. **Plaintiff Robert Mason**

a) On personal knowledge, Plaintiff Robert Mason (hereinafter “Plaintiff” or “Mason”) is an individual who resides in Saginaw County, Michigan. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and vision loss, life-threatening and debilitating conditions. In or around May 2005, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis and vision damage, both serious and potentially disabling medical conditions. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He

consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around May 2005, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Badami prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Badami was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately October 2017, he began to experience shortness of breath, wheezing, trouble breathing, fatigue, coughing, blurry vision, vision loss, dizziness and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and vision loss. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing Amiodarone-induced pulmonary fibrosis and vision loss, Plaintiff was a remarkably healthy and active individual. After developing these injuries, he could not easily exert himself and was often fatigued and weak. He also and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary injury.

49. **Plaintiff Noel Cleckler and Frances Cleckler**

a) On personal knowledge, Plaintiff Noel Cleckler (hereinafter "Plaintiff" or "Cleckler") is an individual who resides in Taylor County, Texas. He was prescribed,

purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease and vision loss, a life-threatening and debilitating condition. In or around 2014, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease and vision injury, a serious and potentially disabling condition. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Patel prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Patel was a victim of the long-term and

successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately 2015, he began to experience vision loss, blurry vision, cataracts, and shortness of breath, wheezing, trouble breathing, coughing,

fatigue, chest pain, weakness, and dizziness. He was presented with a diagnosis of Amiodarone-induced pulmonary disease and vision loss. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing vision injuries and pulmonary disease, Plaintiff was a remarkably healthy and active individual. After developing these complications, he struggles to exert himself and is often short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease and vision loss.

j) Additionally, Plaintiff Frances Cleckler is the spouse of the Plaintiff Noel Cleckler and resides with her spouse, and she depended on Noel Cleckler, to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Noel Cleckler, Plaintiff Frances Cleckler, has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

50. **Plaintiff Mark Laganelli**

a) On personal knowledge, Mark Laganelli, Individually and as Personal Representative of the Estate of Lawrence Laganelli deceased (hereinafter "Plaintiff" or "Laganelli") is an individual who resides in Worcester County, Massachusetts. Mr.

Laganelli was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In or around June 2000, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2000, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Stephen Pezzella prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Stephen Pezella was a victim of the

long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately April 2016, he began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, vision loss, edema,

itching and chest pain. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and respiratory failure. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, he struggled to exert himself, was often weak and suffered frequent pneumonias. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis including vision loss.

j) After developing pulmonary fibrosis his condition deteriorated rapidly, and his lungs collapsed requiring intensive care hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use due to his pneumonia and respiratory failure. After spending several days in the hospital, Lawrence Laganelli succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on August 10, 2016.

51. **Plaintiff Neils Davis**

a) On personal knowledge, Plaintiff Neils Davis (hereinafter "Plaintiff" or "Davis") is an individual who resides in Utah County, Utah. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision

injury and loss as well as pulmonary injury, a life-altering and debilitating condition. In or around September 2014, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss and pulmonary injury, both serious and potentially disabling conditions. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around September 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Chun Hwag prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Chun Hwag was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which

would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately September 2015, he began to experience vision loss, visual disturbances such as halos and floaters, dizziness, poor coordination, shortness of breath, coughing, fatigue, abdominal pain, trouble with exertion, irregular heart rate and weakness. He was presented with a diagnosis of Amiodarone-induced vision loss/injury and pulmonary injury. Amiodarone-induced vision loss is a debilitating

condition that could worsen over time resulting in other visual complications. In addition, Amiodarone-induced pulmonary injury is a debilitating chronic, progressive condition that only worsens over time. The long-term survival rate for individuals with Amiodarone-induced pulmonary injury is extremely poor. Pulmonary injury causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing vision injury and loss and pulmonary complications, Plaintiff was a remarkably healthy and active individual. After developing these injuries, he could not easily read or drive and was often fatigued and short of breath. He also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat his Amiodarone-induced vision injury and pulmonary injury, including congestive heart failure and kidney disease.

52. **Plaintiffs Don Amburgey and Joyce Amburgey**

a) On personal knowledge, Plaintiff Don Amburgey (hereinafter "Plaintiff" or "Amburgey") is an individual who resides in Letcher County, Kentucky. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, vision injury, kidney disease and abnormal thyroid function, all life-threatening and debilitating conditions. In or around January 2009, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his

Amiodarone use, he developed Amiodarone-induced interstitial lung disease, vision loss and impairment, kidney disease, and hypothyroidism. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Arun Rao prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Arun Rao was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation.

Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately August 2017, he began to experience shortness of breath, wheezing, coughing, fatigue, weakness, cataracts, blurred vision, eye pain, vision loss, depression, anxiety, dizziness, weight loss, kidney and thyroid disease. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease, vision injury, kidney disease, and hypothyroidism. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced vision loss, pulmonary, kidney, and thyroid disease, Plaintiff was a remarkably healthy and active individual. After developing these disabling injuries, he struggles to exert himself, cannot leave his home, requires assistance for all daily living activities, and has become depressed. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced injuries.

j) Additionally, Plaintiff Joyce Amburgey is the spouse of the Plaintiff Don Amburgey, and resides with her spouse, and she depended on Don Amburgey to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Don Amburgey, Plaintiff Joyce Amburgey has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

53. **Plaintiff Elbert Crowder**

a) On personal knowledge, Plaintiff Elbert Crowder (hereinafter "Plaintiff" or "Crowder") is an individual who resides in Pulaski County, Arkansas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced blindness and vision injury, a life-altering and debilitating condition. In or around June 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a

“rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced ischemic optic neuropathy, a serious and potentially disabling condition. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In June 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Michael Nolen prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Michael Nolen was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately September 2015, he began to experience blindness, vision loss, eye pain, floaters, loss of visual acuity, and trouble with coordination due to vision loss. He was presented with a diagnosis of Amiodarone-induced blindness, and vision injury including ischemic optic neuropathy. Amiodarone-induced vision loss is a debilitating condition that could worsen over time resulting in other visual complications. Amiodarone-induced ischemic optic neuropathy and blindness often cannot be corrected and causes a significant impairment on quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing vision injury and blindness, Plaintiff was a remarkably healthy and active individual. After developing these injuries, he could not read or drive and requires assistance for daily living activities. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced blindness and vision injury.

54. **Plaintiffs Timothy LeRose and Margaret LeRose**

a) On personal knowledge, Plaintiff Timothy LeRose (hereinafter "Plaintiff" or "LeRose") is an individual who resides in Nicholas County, West Virginia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss, a life-altering and debilitating conditions. In or around August 2014, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced ischemic optic neuropathy, a serious and potentially blinding vision disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a

prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In August 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Chafik Assal prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Chafik Assal was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a

mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately October 2015, he began to experience blurry vision, floaters, loss of peripheral vision, sudden blindness, optic nerve damage, shortness of breath, weight gain, and abnormal thyroid function. He was presented with a diagnosis of Amiodarone-induced ischemic optic neuropathy and blindness. Amiodarone-induced ischemic optic neuropathy is a debilitating chronic, visual eye condition that permanently damages the optic nerve resulting in loss of vision. There are minimal treatment options available for individuals with Amiodarone-induced ischemic optic neuropathy and the outcome is extremely poor.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing optic neuropathy and vision loss, Plaintiff was a remarkably healthy and active individual. After developing vision loss and optic damage, he struggles to drive, read, watch television, and enjoy the things he once did. He also gained weight and suffers from a litany of other health problems related to his use of

Amiodarone and medications used to treat his Amiodarone-induced vision injury including abnormal thyroid function and shortness of breath.

j) Additionally, Plaintiff Margaret LeRose is the spouse of the Plaintiff Timothy LeRose, and resides with her spouse, and she depended on Timothy LeRose to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Timothy LeRose, Plaintiff Margaret LeRose has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

55. **Plaintiff Doyle Turner**

a) On personal knowledge, Doyle Turner, Individually and as Personal Representative of the Estate of Carolyn Turner, deceased (hereinafter "Plaintiff" or "Turner") is an individual who resides in Gregg County, Texas. Mrs. Turner was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute interstitial lung disease, a life-threatening and debilitating condition. In or around October 2014, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease and respiratory failure, both serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she

receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In October 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Gordon Uretsky prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Gordon Uretsky was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not

receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately April 2016, she began to experience vision loss, blurry vision, trouble with coordination due to vision loss, hallucinations and overall weakness, as well as shortness of breath, wheezing, difficulty breathing, coughing, fatigue, and weakness. She was presented with a diagnosis of Amiodarone-induced respiratory failure. Respiratory failure is a debilitating chronic, progressive condition that only worsens over time.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing vision loss and respiratory failure, Plaintiff was a remarkably healthy and active individual. After developing vision loss and respiratory failure, she could no longer enjoy many of the things she used to. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced respiratory failure.

j) After developing respiratory failure, her condition deteriorated rapidly, requiring extended hospitalization. She could not adequately breathe on her own, requiring breathing assistance and oxygen use. Carolyn Turner succumbed to her Amiodarone-induced respiratory failure on April 20, 2017.

56. **Plaintiffs Melvin Kinney and Isabella Kinney**

a) On personal knowledge, Plaintiff Melvin Kinney (hereinafter “Plaintiff” or “Kinney”) is an individual who resides in Chittenden County, Vermont. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening pulmonary condition. In November 2014, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In December 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Vladimir Curkoric prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Vladimir Curkoric was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-

threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately May 2016, he began to experience shortness of breath, wheezing, coughing, trouble breathing, fatigue, chest pain, and difficulty walking. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis is a disease that causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, he struggles to exert himself and requires use of oxygen. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j) Additionally, Plaintiff Isabella Kinney is the spouse of the Plaintiff Melvin Kinney, and resides with her spouse, and she depended on Melvin Kinney to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Melvin Kinney, Plaintiff Isabella Kinney has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel

necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

57. **Plaintiffs Baldamer Martinez and Anna Martinez**

a) On personal knowledge, Plaintiff Baldamer Martinez (hereinafter “Plaintiff” or “Martinez”) is an individual who resides in Galveston County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury and vision loss, both life-threatening and debilitating conditions. In or around May 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease, as well as vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around May 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as

detailed herein below, along with the continuing sales efforts of Defendants, Dr. Acharya prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Acharya was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up-to-date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been

provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2016, he began to experience shortness of breath, wheezing, trouble breathing, fatigue, chest pain, weakness, blurred vision and vision loss, memory loss, dizziness and edema. He was presented with a diagnosis of Amiodarone-induced pulmonary disease and vision loss. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary disease and vision loss, Plaintiff was a remarkably healthy and active individual. After developing pulmonary injury and vision loss, he struggles to exert himself and is often too weak to walk. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease.

j) Additionally, Plaintiff Anna Martinez is the spouse of the Plaintiff Baldemar Martinez, and resides with her spouse, and she depended on Baldemar Martinez to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Baldemar Martinez, Plaintiff Anna Martinez has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel

necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

58. **Plaintiff Albert Shepherd**

a) On personal knowledge, Albert Shepherd, Individually and as Personal Representative of the Estate of Emily Shepherd, deceased (hereinafter “Plaintiff” or “Shepherd”) is an individual who resides in Starke County, Indiana. Mrs. Shepherd was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating pulmonary condition. In October 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis and respiratory failure, serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In October 2011, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Rishi Sukhija prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Rishi Sukhija and Dr. Abul Basher were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up-to-date warning labels that would have warned her of the serious, potentially life-

threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately May 2015, she began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, edema, tremors, dizziness, and weakness. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and respiratory failure. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis and respiratory failure, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, she could not walk across the room and required oxygen. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis and respiratory failure.

j) After developing pulmonary fibrosis and respiratory fibrosis her condition deteriorated rapidly, requiring hospitalization. She could not adequately breathe on her own, requiring breathing assistance and oxygen use. After spending several days in the

hospital, Emily Shepherd succumbed to her Amiodarone-induced pulmonary fibrosis and respiratory failure on October 8, 2016.

59. **Plaintiff Doris Johnson**

a) On personal knowledge, Plaintiff Doris Johnson (hereinafter “Plaintiff” or “Johnson”) is an individual who resides in Knox County, Tennessee. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and pulmonary fibrosis, both life-altering and debilitating conditions. In or around September 2014, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis and vision loss, serious and potentially disabling conditions. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately September 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of

physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Brian Adams prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Brian Adams was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up-to-date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been

provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately July 2015, she began to experience vision loss, deposits in eye, floaters, poor coordination due to vision loss, tremors, trouble breathing, shortness of breath, coughing, weakness, edema, chest pain, and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and vision loss. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary fibrosis and vision loss Plaintiff was a remarkably healthy and active individual. After developing these injuries, she could not easily read or drive and she is often fatigued and short of breath, requiring assistance with daily life activities. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced vision injury and pulmonary fibrosis.

60. **Plaintiff Fred Burrough**

a) On personal knowledge, Plaintiff Fred Burrough (hereinafter "Plaintiff" or "Burrough") is an individual who resides in Garland County, Arkansas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or

distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury, a life-altering and debilitating condition. In or around April 2011, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease, a serious and potentially disabling lung condition. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Rajesh prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Rajesh was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details

and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that her use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up-to-date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2017, he began to experience trouble breathing, coughing, difficulty with exertion, shortness of breath, weakness, pneumonia and fatigue. He was presented with a diagnosis of Amiodarone induced-pulmonary disease. Amiodarone-induced pulmonary disease is a debilitating chronic,

progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary disease, Plaintiff was a remarkably healthy and active individual. After developing these injuries, he was often fatigued and short of breath and required hospitalization. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease.

61. **Plaintiffs Mona Windham and Ronnie Windham**

a) On personal knowledge, Plaintiff Mona Windham (hereinafter "Plaintiff" or "Windham") is an individual who resides in Chester County, South Carolina. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-altering and debilitating lung condition. In or around April 2012, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity, a serious and potentially life-threatening lung condition. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that

Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately April 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Robert Delphia prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Robert Delphia was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not

receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up-to-date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2016, she began to experience trouble breathing, shortness of breath, coughing, weakness, edema, dizziness, chest pain, and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture,

distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary toxicity Plaintiff was a remarkably healthy and active individual. After developing pulmonary toxicity, she is often fatigued and short of breath and requires assistance with daily life activities. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary toxicity.

j) Additionally, Plaintiff Ronnie Windham is the spouse of the Plaintiff Mona Windham, and resides with his spouse, and he depended on Mona Windham to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Mona Windham, Plaintiff Ronnie Windham has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

62. **Plaintiffs William Hunt and Phyllis Hunt**

a) On personal knowledge, Plaintiff William Hunt (hereinafter "Plaintiff" or "Hunt") is an individual who resides in New Haven County, Connecticut. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss, a life-altering and debilitating condition. In or around October 2003, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity, a potentially life-threatening pulmonary disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had

not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Cardido and Dr. Batsford prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Cardido and Dr. Batsford were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required

Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up-to-date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2016, he began to experience trouble breathing, shortness of breath, coughing, weakness, edema, dizziness, chest pain, edema and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and

sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary toxicity, Plaintiff was a healthy and very active individual. After developing Amiodarone-induced pulmonary toxicity, he can no longer work or swim, and requires full time use of oxygen. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease.

j) Additionally, Plaintiff Phyllis Hunt is the spouse of the Plaintiff William Hunt, and resides with her spouse, and she depended on William Hunt to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff William Hunt, Plaintiff Phyllis Hunt has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

63. **Plaintiffs Pink and Annie Jones**

a) On personal knowledge, Plaintiff Pink Jones (hereinafter "Plaintiff" or "Jones") is an individual who resides in Bradley County, Tennessee. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease and vision damage, both life-altering and debilitating conditions. In or around January 2011 he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease, pulmonary toxicity and vision damage, potentially life-threatening diseases. He received no warning from his physician about these potential life-threatening complications, nor

did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2011, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Brian Mitchell prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mitchell was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required

Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately August 2017, he began to experience trouble breathing, shortness of breath, coughing, weakness, vision loss, dizziness, chest pain, headaches and fatigue. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease and pulmonary toxicity and corneal deposits causing vision damage. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and

sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced interstitial lung disease and pulmonary toxicity and vision damage, Plaintiff was a healthy and very active individual. After developing these Amiodarone-induced complications, he is often weak and short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease.

j) Additionally, Plaintiff Annie Jones is the spouse of the Plaintiff Pink Jones, and resides with her spouse, and she depended on Pink Jones to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Pink Jones, Plaintiff Annie Jones has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

64. **Plaintiff Mary Davis**

a) On personal knowledge, Plaintiff Mary Davis (hereinafter "Plaintiff" or "Davis") is an individual who resides in Waukesha County, Wisconsin. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-altering and debilitating condition. In or around January 2012, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that

Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately January 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth and other Defendants to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. J. Wright prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Wright was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not

receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up-to-date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2017, she began to experience shortness of breath, wheezing, trouble breathing, fatigue, chest pain, weakness, and vision loss. She was presented with a diagnosis of Amiodarone-induced pulmonary. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture,

distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, she can no longer walk daily, and she struggles to exert herself, and requires use of oxygen. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

65. **Plaintiffs James Mason and Cathy Mason**

a) On personal knowledge, Plaintiff James Mason (hereinafter “Plaintiff” or “Mason”) is an individual who resides in Llano County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and vision loss, both life-altering and debilitating conditions. In or around January 2006, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a potentially life-threatening pulmonary disease, and vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2006, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Muse and Dr. McCarland prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Muse and Dr. McCarland were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and

notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up-to-date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately October 2016, he began to experience trouble breathing, shortness of breath, coughing, wheezing, weakness, dizziness, chest pain, vision loss and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and vision loss. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing Amiodarone-induced pulmonary fibrosis and vision loss, Plaintiff was a healthy and very active individual. After developing Amiodarone-induced pulmonary fibrosis, he struggles to exert himself and is often short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j) Additionally, Plaintiff Cathy Mason is the spouse of the Plaintiff James Mason, and resides with her spouse, and she depended on James Mason to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff James Mason, Plaintiff Cathy Mason has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

66. **Plaintiffs Cecil Thomas and Debbie Thomas**

a) On personal knowledge, Plaintiff Cecil Thomas (hereinafter "Plaintiff" or "Thomas") is an individual who resides in Union County, North Carolina. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss, life-threatening and debilitating conditions. In February 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced total vision loss, a serious and permanently disabling blindness due to ischemic optic neuropathy. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In February 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Glen Fandetti prescribed him a course of 400mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Glen Fandetti was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required

labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately June 2015, he began to experience vision and vision loss, blindness, headaches, poor coordination, and dizziness. He was presented with a diagnosis of Amiodarone-induced ischemic optic neuropathy in both eyes, causing total blindness. Amiodarone-induced blindness is a debilitating chronic condition that is unlikely to improve resulting in significant disability.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing Amiodarone-induced blindness, Plaintiff was a remarkably healthy and active individual. After developing vision loss, he could no longer work, drive or read, and requires full time assistance with daily life activities. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced optic injury.

j) Additionally, Plaintiff Debbie Thomas is the spouse of the Plaintiff Cecil Thomas, and resides with her spouse, and she depended on Cecil Thomas to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Cecil Thomas, Plaintiff Debbie Thomas has in

the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

67. **Plaintiff Martha Sue Dixon**

a) On personal knowledge, Plaintiff Martha Sue Dixon (hereinafter "Plaintiff" or "Dixon") is an individual who resides in Pike County, Mississippi. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary and thyroid disease, life-threatening and debilitating conditions. In or around October 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary disease and thyroid injury, both serious and potentially disabling conditions. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Wyeth

and/or the Generic Defendants and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In October 2011, as a result of the long-term and pervasive promotional activities of brand innovator Defendant Wyeth and other Defendants to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Ali Reza Homyuni prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by the Brand and/or Generic Defendants. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Ali Reza Homyuni was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) She was not aware that her use of the medication was for an “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an “off-label” use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Defendants to McKesson and/or by McKesson to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in or around 2012, she began to experience trouble breathing, coughing, dizziness, weakness, weight fluctuations, chest pain, difficulty with exertion and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary disease and thyroid damage. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing thyroid injury and pulmonary complications, Plaintiff was a remarkably healthy and active individual. After developing these injuries, she was often fatigued and short of breath. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced thyroid injury and pulmonary disease.

68. **Plaintiff Belva Ward**

a) On personal knowledge, Plaintiff Belva Ward (hereinafter "Plaintiff" or "Ward") is an individual who resides in Scott County, Tennessee. She was prescribed,

purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-altering and debilitating condition. In or around January 2008, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially disabling lung condition. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Wyeth and/or the Generic Defendants and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In or around February 2008, as a result of the long-term and pervasive promotional activities of brand innovator Defendant Wyeth and other Defendants to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Clint Doiron prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by the Brand and/or Generic Defendants. She

filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Clint Doiron was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Defendants to McKesson and/or by McKesson to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2015, she began to experience shortness of breath, trouble breathing, coughing, wheezing, pulmonary edema, bruising, and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis, she was often fatigued and short of breath, resulting in frequent pneumonias and hospitalizations. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary injuries.

69. **Plaintiffs Donald Bard and Judy Bard**

a) On personal knowledge, Plaintiff Donald Bard (hereinafter "Plaintiff" or "Bard") is an individual who resides in Okaloosa County, Florida. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced lung toxicity, a life-threatening and debilitating condition. In or around September 1997, he was diagnosed as suffering from A-fib, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his

cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Wyeth and/or the Generic Defendants and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In September 1997, as a result of the long-term and pervasive promotional activities of brand innovator Defendant Wyeth and other Defendants to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Simone Musco prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by the Brand and/or Generic Defendants. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Musco was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Defendants to McKesson and/or by McKesson to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately April 2016, he began to experience shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with pulmonary toxicity is extremely poor. Amiodarone-induced

pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary toxicity, Plaintiff was a remarkably healthy and active individual. After developing pulmonary toxicity, he could not walk across the room. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

j) Additionally, Plaintiff, Judy Bard, is the spouse of the Plaintiff Donald Bard, and resides with her spouse, and she depended on Donald Bard to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Donald Bard, Plaintiff Judy Bard has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

70. **Plaintiffs John Spaulding, Jr. and Linda Spaulding**

a) On personal knowledge, Plaintiff John Spaulding Jr. (hereinafter "Plaintiff" or Spaulding") is an individual who resides in Miller County, Arkansas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and injury, a life-altering and debilitating condition. In or around April 2004, he was diagnosed as suffering from atrial fibrillation, which is a rhythm

condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss and injury, a serious and potentially debilitating eye disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Wyeth and/or the Generic Defendants and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In June 2004, as a result of the long-term and pervasive promotional activities of brand innovator Defendant Wyeth and other Defendants to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. James Hurley prescribed him a course of 800mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by the Brand and/or Generic Defendants. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. James Hurley was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating

atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Defendants to McKesson and/or by McKesson to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately December 2006, he began to experience vision loss, decline in visual acuity, unequal pupils, eye irritation and pain, fatigue and dizziness, and poor coordination due to vision loss. He was subsequently presented with a diagnosis of Amiodarone-induced vision loss and injury. Amiodarone-induced vision loss is a debilitating condition that could worsen over time resulting in other visual

complications, including, but not limited to, eye pain, irritation, floaters, retinal detachment, corneal disease, optic neuropathy, loss of visual acuity and peripheral vision, deposits within the eye, and cataracts. Amiodarone-induced vision loss and injury often cannot be corrected and causes a significant impairment on quality of life.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing vision loss and injury, Plaintiff was a remarkably healthy and active individual. After developing vision loss/injury, he could not easily read or drive. He also and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone induced vision loss/injury.

j) In or about June 2016, his family discovered a Facebook page, discussing the serious complications of Amiodarone, including vision loss and injury, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his injuries. The Facebook page in question was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries he suffered were caused by wrongdoing on the part of the Defendants.

k) Additionally, Plaintiff Linda Spaulding is the spouse of the Plaintiff John Spaulding, Jr., and resides with her spouse, and she depended on John Spaulding, Jr. to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff John Spaulding, Jr., Plaintiff Linda Spaulding has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

71. **Plaintiffs Shirley Miller and Ronald Miller**

a) Plaintiff Shirley Miller (hereinafter “Miller” or “Plaintiff”) is an individual who resides in Maricopa County, Arizona. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary complications, along with other serious injuries. In January 2015, Plaintiff was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. Miller was subsequently prescribed a “rhythm medication” by a cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she suffered severe physical, economic and emotional injuries, including, but not limited to, severe lung injury. She received no warning from her physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone is manufactured and/or distributed by Defendants. She consumed Amiodarone manufactured by Teva and potentially other Generic Defendants, and promoted and sold for “off-label” use by Defendants Wyeth and the other Generic Defendants, and which was distributed nationwide by McKesson.

d. Beginning in late March 2015, as a result of the long-term and pervasive promotional activities of brand innovator Defendant Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of the Generic Defendants, including Teva, Dr. Reddy Atmakuri prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The

prescriptions were a generic brand version of Amiodarone manufactured by Teva and/or the other Generic Defendants. She filled the prescription and ingested the drug Amiodarone as prescribed. This physician was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e. She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Wyeth, and Teva or the other Generic Defendants to McKesson and/or by McKesson to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f. In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was

not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g. Beginning in approximately May 2015, she began to experience increased heart rate, shortness of breath, extreme exhaustion, weakness, headaches, poor balance, bleeding and bruising, difficulty breathing and concentrating, memory loss, hypertension, edema, loss of taste, significant loss of weight, adverse effects on her liver and depression.

h. In July 2015, she was admitted to the hospital with a variety of reported issues and weight loss, where she was kept for several days. However, it was not until October 2015 that a hematologist suggested these complications may be the result of Amiodarone use in terms of the amount she was taking, and later a neurologist recommended she stop taking Amiodarone altogether. It was during October 2015 that she was diagnosed with having developed pulmonary infiltrates and skin lesions, along with other complications attributable to Amiodarone toxicity.

i. She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

j. Before developing Amiodarone-induced toxicity and pulmonary complications, she was a healthy and active individual. She spent a great deal of enjoying many outdoor activities. Only a few months later, after starting Amiodarone, her quality of life and that of her family was significantly impaired. She used to read 3 to 5 novel books a week but now can no longer read even a short novel and must frequently go back into the text to remember who the characters are and what the plot is about. She is tearful and has frequent episodes of anger and confusion as she can't remember how to cook simple recipes that she has cooked all her adult life, or which cupboard she has placed things. Often, she finds herself lost in her own kitchen of 20 years. Even after

discontinuing the drug she still has a poor appetite due to her altered sense of taste and smell and can no longer enjoy the smell or taste of coffee, the taste of tea and sugar, and must ask her family or others to taste any food that she prepares. She is often fearful as her life has been dramatically altered and she is not the same person she used to be.

k. Additionally, Plaintiff, Ronald Miller, is the spouse of the Plaintiff Shirley Miller, and resides with his spouse, and he depended on Shirley Miller to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Shirley Miller, Plaintiff Ronald Miller has in the past and will in the future suffer and incur loss of his consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for her, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

72. **Plaintiff Jacqueline Fabbri**

a) Jacqueline Fabbri, individually and as Personal Representative of the Estate of Frank Fabbri, deceased (hereinafter "Fabbri") is an individual who resides in San Luis Obispo County, California. Mr. Fabbri was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In October 2015, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In October 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Lorianna Fletcher prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Lorianna Fletcher was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially

other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately July 2016, he began to experience many of the symptoms outlined in the Medication Guide, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Prior to developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room and suffered frequent pneumonias. He also lost suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j) After developing pulmonary fibrosis his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After spending several days in the hospital, Frank Fabbri succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on September 6, 2016.

73. **Plaintiff Inga Reynolds**

a) Inga Reynolds, individually and as Personal Representative of the Estate of Gerwin Hermenau, deceased (hereinafter “Hermaneau”) is an individual who resides in Riverside County, California. Mr. Hermenau was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In or around January 2015, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he

receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In approximately January 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Sanyasi Ganta prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Ganta was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that

Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately August 2016, he began to experience many of the symptoms outlined in the Medication Guide, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Prior to developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room and suffered frequent pneumonias. He also lost suffered from a litany of other

health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j) After developing Amiodarone-induced pulmonary fibrosis his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After spending three weeks in the hospital, Gerwin Hermenau succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on October 1, 2016.

74. **Plaintiff Carletta Williams**

a) Carletta Williams, individually and as Personal Representative of the Estate of James C. Williams, III, deceased (hereinafter “Williams”) is an individual who resides in Lucas County, Ohio. Mr. Williams was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced pulmonary disease and vision loss, both serious and potentially disabling conditions. In or around 2010, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease and vision loss, both serious and potentially debilitating conditions. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Paul Berlacher prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Berlacher was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications,

as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately 2012, he began to experience many of the symptoms outlined in the Medication Guide, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, blurred vision, vision loss, and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary disease and vision loss. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary disease is extremely poor. Pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Prior to developing Amiodarone-induced pulmonary disease and vision loss, Plaintiff was a remarkably healthy and active individual. After developing pulmonary disease and vision loss, he struggled to exert himself and was often short of breath and fatigued. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease and vision loss.

j) After developing pulmonary disease and vision loss, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After spending significant time in the hospital, James C. Williams, III succumbed to his Amiodarone-induced pulmonary disease and respiratory failure on February 7, 2017.

75. **Plaintiffs Trio Caldwell and Beverly Caldwell**

a) Plaintiff Trio Caldwell (hereinafter “Plaintiff” or “Caldwell”) is an individual who resides in Maricopa County, Arizona. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Ischemic Optic Neuropathy, which is a debilitating condition related to the eyes resulting in blindness and reduced loss of vision. In or around August 2013, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Ischemic Optic Neuropathy. He received no warning from his physician about these potential severe complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around August 2013 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Arman Talle prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Arman Talle was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-

threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in the spring of 2015, he began to experience vision loss, optic nerve damage, degenerative vision changes, and blindness. After several medical evaluations and treatments for visual complications, he was presented with a diagnosis of Ischemic Optic Neuropathy. This condition is debilitating, chronic condition that makes it very difficult to see, and drastically reduces the quality of life. Due to this debilitating diagnosis.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing Ischemic Optic Neuropathy, he was a remarkably healthy and active individual. After developing Optic Neuropathy, he now struggles with daily life functions due to his visual impairment. He is unable to enjoy the activities he once loved due to his vision loss.

j) Additionally, Plaintiff, Beverly Caldwell is the spouse of the Plaintiff Trio Caldwell, and resides with her spouse, and she depended on Trio Caldwell to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Trio Caldwell, Plaintiff Beverly Caldwell has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

76. **Plaintiffs Edwin Streed and Margaret Streed**

a) Plaintiff, Edwin Streed (hereinafter “Plaintiff” or “Streed”) is an individual who resides in Alameda County, California. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In approximately 2005, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In 2005, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth, along with the continuing sales efforts of Defendants, Dr. Stephen C. Remole prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the

prescription and ingested the drug Amiodarone as prescribed. Dr. Remole was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) In approximately July 2015, his heart condition became worse. Dr. Remole doubled his Amiodarone does to 400 mg. In approximately October 2015, he began to experience many of the symptoms outlined in the Medication Guide, which include increased heart rate, shortness of breath, extreme exhaustion, and coughing.

h) In October 2015, he was admitted to the hospital with an initial diagnosis of pneumonia. Eventually his condition worsened, a high definition CT scan was performed, which revealed lung changes not typical of pneumonia. The CT scan revealed he had Amiodarone toxicity and pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

i) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

j) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. He spent a great deal of time with his family and enjoyed doing chores around the home. Only a few months later, after developing pulmonary fibrosis, he could not walk across the room without being short of breath, coughing and increased heart rate. He suffers from a litany of other health problems related to his use of Amiodarone, including acute pulmonary edema, and vision problems.

k) Additionally, Plaintiff, Margaret Streed is the spouse of the Plaintiff Edwin Streed, and resides with her spouse, and she depended on Plaintiff, Edwin Streed to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff, Edwin Streed, Plaintiff, Margaret Streed has in the past and will in the future suffer and incur loss of his consortium, loss of her

spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

77. **Plaintiffs Dianne Cruce and Doug Hyak**

a) On personal knowledge, Plaintiff Dianne Cruce (hereinafter "Plaintiff" or "Cruce") is an individual who resides in San Luis Obispo County, California. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating lung condition. In or around October 2009, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity, a serious and potentially life-threatening lung condition. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for "off-label" use by them.

d) In approximately April 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Devi Pondicherry prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Pondicherry was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up-to-date warning labels that would have warned her of the serious, potentially life-

threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately June 2016, she began to experience trouble breathing, shortness of breath, wheezing, coughing, pulmonary hypertension, weakness, edema, nervousness, chronic pain, and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary toxicity Plaintiff was a healthy and active individual. After developing pulmonary toxicity, she was often weak and struggled to walk across the room. She also had weight fluctuations and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary toxicity.

j) Additionally, Plaintiff Doug Hyak is the spouse of the Plaintiff Dianne Cruce, and resides with his spouse, and he depended on Dianne Cruce to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Dianne Cruce, Plaintiff Doug Hyak has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost

and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

78. **Plaintiffs Dameon Albritton and Ji Yong Ahn**

a) On personal knowledge, Plaintiff Dameon Albritton (hereinafter “Plaintiff” or “Albritton”) is an individual who resides in Sacramento County, California. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating condition. In or around March 2013, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease, a serious and potentially deadly lung disease, as well as vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In March 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Kozina prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Kozina was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-

threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately September 2013, he began to experience many of the symptoms outlined in the Medication Guide, including shortness of breath, wheezing, difficulty breathing, fatigue, chest pain, weakness, abdominal pain, nausea, vomiting, blurred vision and vision loss. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary toxicity, Plaintiff was a remarkably healthy and active individual. After developing pulmonary toxicity he struggles to exert himself and to enjoy the things he once did. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

j) Additionally, Plaintiff Ji Yong Ahn is the spouse of the Plaintiff Dameon Albritton, and resides with her spouse, and she depended on Dameon Albritton to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Dameon Albritton, Plaintiff Ji Yong Ahn has

in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

79. **Plaintiffs Laurel Turley and Roger Turley**

a) On personal knowledge, Plaintiff Laurel Turley (hereinafter "Plaintiff" or "Turley") is an individual who resides in Belmont County, Ohio. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease and thyroid disease, both life-threatening and debilitating condition. In or around June 2012, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for "off-label" use by them.

d) In June 2012 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Adele Frenn prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Frenn was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-

threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately 2015, she began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain, edema, and abnormal thyroid function. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease and hypothyroidism. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced lung disease and thyroid toxicity, she was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary disease and hypothyroidism, she struggles to exert herself and is often weak and short of breath. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary disease and hypothyroidism.

j) Additionally, Plaintiff, Roger Turley is the spouse of the Plaintiff Laurel Turley, and resides with his spouse, and he depended on Laurel Turley to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Laurel Turley, Plaintiff Roger Turley has in the past and will in

the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for her, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

80. **Plaintiff Diane Mancinelli**

a) On personal knowledge, Plaintiff Diane Mancinelli (hereinafter "Plaintiff" or "Mancinelli") is an individual who resides in Nevada County, California. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, a life-threatening and debilitating condition. In or around January 2014, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for "off-label" use by them.

d) In or around January 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Ryan Smith prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Ryan Smith was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-

threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2018, she began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain and difficulty walking. She was presented with a diagnosis of Amiodarone-induced pulmonary disease. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced pulmonary disease, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary disease, she struggles with frequent pneumonias and is often weak and short of breath, requiring hospitalization at times. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary injuries.

81. **Plaintiff Connie Luye**

a) On personal knowledge, Connie Luye, Individually and as Personal Representative of the Estate of Evelyn Moss, deceased (hereinafter "Plaintiff" or "Moss") is an individual who resides in St. Francois, Missouri. Evelyn Moss was prescribed,

purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating pulmonary condition. In January 2013, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis and respiratory failure, serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In January 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Michael Shapiro prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Shapiro was a victim of the long-

term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up-to-date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately April 2016, she began to experience shortness of breath, wheezing, abnormal kidney function, chest pain, coughing, vision loss, fatigue,

weakness, and abnormal thyroid function. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and respiratory failure, as well as kidney failure and hypothyroidism. These debilitating, chronic, progressive conditions only worsen over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, respiratory failure, kidney failure and hypothyroidism, Plaintiff was a remarkably healthy and active individual. After developing these conditions she struggled to breathe and exert herself, and could no longer independently perform daily life activities, and these complications resulted in frequent hospitalizations. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis, respiratory failure, kidney failure, and hypothyroidism.

j) After developing pulmonary fibrosis, respiratory fibrosis, kidney failure, and hypothyroidism, her condition deteriorated rapidly, requiring hospitalization. She could not adequately breathe on her own and developed pneumonia, requiring breathing assistance and oxygen use. After spending several days in the hospital, Evelyn Moss succumbed to her Amiodarone-induced pulmonary fibrosis, respiratory failure, and kidney failure on September 22, 2017.

82. **Plaintiff Robert E. Smith**

a) On personal knowledge, Plaintiff Robert E. Smith (hereinafter “Plaintiff” or “Smith”) is an individual who resides in Onondaga County, New York. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around November 2014, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In November 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Norman Jafe prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life

threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by the Brand and/or Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Norman Jafe was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an "off-label" use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the

serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately August 2017, he began to experience many of the symptoms outlined in the Medication Guide, which include trouble breathing, shortness of breath, wheezing, weakness, dizziness, chest pain, tremors and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing pulmonary fibrosis, he was a healthy and very active individual. After developing pulmonary fibrosis, he struggles to exert himself and is often short of breath requiring oxygen. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

83. **Plaintiff Dorlis Lyle**

a) Dorlis Lyle, individually and as Executor of the Estate of James Lyle, deceased (hereinafter "Lyle") is an individual who resides in Pettis County, Pennsylvania. Mr. Lyle was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced acute pulmonary toxicity and respiratory failure, life-threatening and debilitating conditions. In June 2010, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the

heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary toxicity and respiratory failure, serious and potentially deadly lung conditions. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In June 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Sedalia prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Sedalia was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately September 2017, he began to experience many of the symptoms outlined in the Medication Guide, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, trouble walking and respiratory failure. He was presented with a diagnosis of Amiodarone-induced adult respiratory distress syndrome and pulmonary failure. Amiodarone-induced toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely

poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for the lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Prior to developing Amiodarone-induced lung disease and pulmonary failure. Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, he struggled to exert himself and was debilitated with weakness and shortness of breath, requiring hospitalization. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

j) After developing Amiodarone-induced pulmonary toxicity and respiratory failure, his condition deteriorated rapidly requiring hospitalization. He could not adequately breathe on his own, requiring oxygen assistance. After spending several days in the hospital, James Lyle succumbed to his Amiodarone-induced adult respiratory distress syndrome and respiratory failure on September 18, 2017.

84. **Plaintiffs George L. Bush and Edwin Martin**

a) Plaintiff George L. Bush (hereinafter "Plaintiff" or "Bush") is an individual who resides in Multnomah County, Oregon. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced pulmonary toxicity, a life-threatening and debilitating condition. In December 2016, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his

Amiodarone use, he developed Amiodarone-induced pulmonary toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In December 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Teva and potentially other manufacturers, Dr. Blair and Dr. Halperin prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Blair and Dr. Halperin were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately May 2018, he began to experience many of the symptoms outlined in the Medication Guide, which include trouble breathing, shortness of breath, coughing, sheezing, weakness, dizziness, chest pain, difficulty walking and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor.

Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Prior to developing Amiodarone-induced pulmonary toxicity, Plaintiff was a healthy and very active individual. After developing Amiodarone-induced pulmonary toxicity, he struggles to exert himself and is often short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

j) Additionally, Plaintiff, Edwin Martin is the spouse of the Plaintiff George L. Bush, and resides with his spouse, and he depended on George L. Bush to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff George L. Bush, Plaintiff Edwin Martin has in the past and will in the future suffer and incur loss of his consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for him.

85. **Plaintiffs Charles Hershiser and Mary Frances Hershiser**

a) On personal knowledge, Plaintiff Charles Hershiser (hereinafter "Plaintiff" or "Hershiser") is an individual who resides in Baldwin County, Alabama. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease and pulmonary toxicity, both life-altering and debilitating conditions. In or around June 2015 he was diagnosed as suffering from atrial fibrillation,

which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease and pulmonary toxicity, potentially life-threatening diseases. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Jason Cole prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Cole was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately January 2018, he began to experience trouble breathing, shortness of breath, coughing, weakness, chest pain, and fatigue. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease and pulmonary toxicity. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor.

Amiodarone-induced interstitial lung disease pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Prior to developing Amiodarone-induced interstitial lung disease and pulmonary toxicity, Plaintiff was a healthy and very active individual. After developing these Amiodarone-induced complications, he struggles to exert himself and can no longer enjoy the activities he once did. In addition, he has suffered from severe difficulty breathing, requiring hospitalization. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced interstitial lung disease and pulmonary toxicity.

j) Additionally, Plaintiff Mary Frances Hershiser is the spouse of the Plaintiff Charles Hershiser, and resides with her spouse, and she depended on Charles Hershiser to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Charles Hershiser, Plaintiff Mary Frances Hershiser has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

86. **Plaintiff Shelby Campbell**

a) Plaintiff, Shelby Campbell (hereinafter "Plaintiff" or "Campbell") is an individual who resides in Muscogee County, Georgia. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a

life-threatening and debilitating condition. In approximately January 2015, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, she developed Amiodarone-induced interstitial lung disease, a potentially life-threatening pulmonary disease, as well as kidney damage. She received no warning from her physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to her, she was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did she receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. She consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In January 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Mahesh Patel prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mahesh Patel was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation,

which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it.

e) She was not aware that her use of the medication was for an "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva and her prescription was for an "off-label" use. More importantly, she did not receive the required Medication Guide for the prescriptions she filled. She did not receive the Medication Guide from her pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with her prescription in sufficient quantities, if at all. Because she did not receive the Medication Guide that Defendants were required to provide her, she received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. She was thus unaware of the dangers she faced from the drug that caused her debilitating injuries.

f) In addition to not receiving the Medication Guide, she was not provided up to date warning labels that would have warned her of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to her. Had she been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, she would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately March 2018, she began to experience many of the symptoms outlined in the Medication Guide, which include trouble breathing, shortness of breath, coughing, wheezing, weakness, kidney damage, and fatigue. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease and kidney failure. Amiodarone-induced interstitial lung disease is a debilitating chronic,

progressive lung condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

i) Before developing Amiodarone-induced interstitial lung disease and kidney failure, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced interstitial lung disease and kidney damage, she struggles to exert herself. As a result of these injuries, she suffers from frequent pneumonias resulting in hospitalization and intensive care. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced interstitial lung disease and kidney damage.

87. **Plaintiff Penny Watson**

a) Penny Watson, individually and as Personal Representative of the Estate of Darwin Watson, deceased, (hereinafter "Mrs. Watson") is an individual who resides in Harrison County, West Virginia. Mr. Watson was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary toxicity, thyroid toxicity, and kidney damage, all life-threatening and debilitating conditions. In January 2012, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary toxicity,

respiratory failure, thyroid toxicity, and kidney damage, all serious and potentially deadly conditions. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around January 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, Dr. Wissam Gharib prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Wissam Gharib was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone® or its

bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) Beginning in approximately March 2018, he began to experience many of the symptoms outlined in the Medication Guide, which include shortness of breath, trouble breathing, coughing, fatigue, anxiety, confusion, hallucinations, severe weakness, abnormal kidney, thyroid and lung function, and respiratory failure. Amiodarone-induced pulmonary toxicity is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damages, scarred and thickened, making it difficulty for lungs to work properly.

h) Prior to developing Amiodarone-induced pulmonary toxicity, thyroid toxicity, pulmonary failure, and kidney disease, Plaintiff was a healthy and active individual. After developing Amiodarone-induced injuries, he could no longer walk, required oxygen supplementation, suffered pneumonia, went into cardiac arrest, developed severe hypothyroidism requiring frequent and lengthy hospitalizations. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity, including kidney disease and Myxedema Coma.

i) After developing Amiodarone-induced pulmonary and thyroid toxicity, respiratory failure and kidney disease, his condition deteriorated rapidly requiring hospitalization. He could not adequately breathe on his own, requiring intubation and ventilation assistance. After spending several days in the hospital, Darwin Watson succumbed to his Amiodarone-induced pulmonary toxicity, thyroid toxicity and respiratory failure on September 18, 2018.

88. **Plaintiffs John Hendrix and Linda Perry**

a) Plaintiff, John Hendrix (hereinafter “Plaintiff” or “Hendrix”) is an individual who resides in East Baton Rouge County, Louisiana. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around 2010, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life threatening complications, nor did any warnings that Amiodarone had not

been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time Amiodarone was prescribed to him, he was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation. Nor did he receive the FDA-mandated Medication Guide the FDA requires to be distributed with a prescription of Amiodarone, which warns the user of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. He consumed Amiodarone; more particularly the Amiodarone manufactured by Teva and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth, along with the continuing sales efforts of Defendants, Dr. Kevin Kilpatrick prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Teva and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Kilpatrick was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it.

e) He was not aware that his use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA approved use of Cordarone®, Pacerone® or its bioequivalents, including the generic formulation sold by Teva, and his prescription was for an “off-label” use. More importantly, he did not receive the required Medication Guide for the prescriptions he filled. He did not receive the Medication

Guide from his pharmacist because the Medication Guides were not provided by Teva and potentially other manufacturers and distributors to pharmacists for distribution with his prescription in sufficient quantities, if at all. Because he did not receive the Medication Guide that Defendants were required to provide him, he received and ingested a mislabeled drug under Delaware State law based on duties imposed under Delaware state law to not manufacture, distribute or sell medications without all required labels and notifications, as set forth in detail below. He was thus unaware of the dangers he faced from the drug that caused his debilitating injuries.

f) In addition to not receiving the Medication Guide, he was not provided up to date warning labels that would have warned him of the serious, potentially life-threatening, side-effects of Amiodarone. Defendants were responsible for ensuring that the appropriate warning labels and Medication Guide were provided to him. Had he been provided the Medication Guide and other appropriate warnings that this medication was not approved or appropriate for the treatment of A-fib, he would have been aware of the serious, potentially life-threatening side effects and would not have taken Amiodarone.

g) In approximately February 2017, he began to experience many of the symptoms outlines in the Medication Guide, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, chest pain, weakness, and dizziness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

h) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

i) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he struggles to exert himself and requires oxygen. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j) Additionally, Plaintiff, Linda Perry is the spouse of the Plaintiff John Hendrix, and resides with her spouse, and she depended on Plaintiff, John Hendrix to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff, John Hendrix, Plaintiff, Linda Perry has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

Defendants

89. Defendant Teva Pharmaceuticals USA, Inc. is a domestic business corporation with its principal place of business in Delaware. Defendant Teva regularly conducts business throughout the United States and is involved in the manufacture, distribution, marketing, promotion, sale, labeling, and/or design of Amiodarone in this State and throughout the United States as detailed below.

90. The true and precise names, roles and capacities of Defendants named as DOES 1-50, inclusive, are currently unknown to Plaintiffs and, therefore, are designated and named as Defendants under fictitious names. Plaintiffs will identify their true identities and their involvement in the wrongdoing at issue if and when they become known. These corporations and entities may include other manufacturers, promoters or distributors of the products at issue.

91. Defendants' conduct described herein was undertaken or authorized by officers or managing agents who were responsible for supervision and operations decisions relating to the manufacture, marketing, promotion, sale and/or distribution of Amiodarone and the

mandated Medication Guide. The described conduct of said entities, managing agents and/or individuals was therefore undertaken on behalf of or in concert with Defendants. Defendants further had advance knowledge of the actions and conduct of said individuals whose actions and conduct were ratified, authorized, and approved by managing agents. At all times relevant hereto, Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, promoting, marketing and/or otherwise introducing into interstate commerce, either directly or indirectly through third parties, the prescription drug Amiodarone from and throughout this State and nationwide.

92. Defendants, acting in concert along with companies such as Wyeth and other generic manufacturers of Amiodarone as well as the distributors thereof, have engaged in a calculated and coordinated campaign of silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the use of Cordarone®/Amiodarone as an indicated treatment for A-fib even though Amiodarone was approved only as a drug of “last resort” for recurrent, life-threatening ventricular fibrillation/tachycardia for whom all other treatment options had failed. Defendants did so because the prospect of significant future profits outweighed their concern regarding health and safety issues, all to the significant detriment of the public and Plaintiffs. Defendants thus engaged in a conspiracy with Wyeth and other generic drug manufacturers to suppress material facts from all Plaintiffs as set forth below. But for the conspiracy between and amongst these companies and their failure to meet their joint and several obligations to warn, including ensuring a Medication Guide in compliance with FDA regulations was delivered and that Defendants also complied with their duties under state law, the Plaintiffs would not have suffered the damages and harms detailed herein. Defendants were able to be the beneficiaries of, took advantage of, the promotional efforts of Wyeth and/or other generic manufacturers of Amiodarone, both in terms of Cordarone®, Pacerone® and other bioequivalent medications, as a result of such conduct. The aforementioned acts of concealment by Defendants served to prevent Plaintiffs and their doctors from learning: (1) Amiodarone was not FDA-

approved for the treatment of atrial fibrillation and that they were taking the drug on an “off-label” basis; (2) by law, Plaintiffs were supposed to receive the Medication Guide with their prescription of Amiodarone in the form required by law; and (3) that Amiodarone-induced pulmonary fibrosis and the other ailments set forth above are not extremely rare side effects of Amiodarone use but rather sufficiently common that the FDA requires Defendants to warn physicians and users of this risk. Any statutes of limitation are tolled during the continuation of this conspiracy, which is on-going.

93. Defendants also had joint and several duties with the distributors of Amiodarone including, but not limited to, ensuring the FDA required Medication Guide meets the requirements set out in 21 C.F.R. §208.20 and ensuring the Medication Guide is distributed to pharmacies and patients in compliance with 21 C.F.R. §208.24. This requirement specifically was to ensure this guide was provided directly to consumers and not their physicians, thus not implicating any aspect of the learned intermediary defense.

94. The companies identified above acted, aided, and abetted Defendant Teva not to disclose the material facts stated herein and/or not to properly distribute the Medication Guide to the consumers who were required to receive such Guides, with such conduct authorized and/or acted on by and through its officers, employees, agents, servants, and/or representatives, including those actively engaged in the legal defense of Defendants.

95. Each reference made in this Complaint to Defendant Teva and DOES 1-50 includes their respective predecessors, successors, parents, subsidiaries, affiliates, and divisions of the corporation for the corresponding time period in any way involved in the design testing, manufacture, distribution, sale or use of Amiodarone.

JURISDICTION AND VENUE

96. Jurisdiction over Defendants is proper because they are either a corporation organized and existing or with their principal place of business located in this State and/or have purposely availed themselves of the privilege of conducting business activities in this State because they currently maintain systematic and continuous

business contacts with this State, and/or based on the allegations of conspiratorial conduct and aiding and abetting as set forth throughout this Complaint. There is complete diversity between Plaintiffs and Defendants, and the amount in controversy is in excess of \$75,000 per Plaintiff.

97. Venue is proper in this District because Defendants conduct business in this District and base their operations here. Defendants' commercial activities in this District include, but are not limited to, the promotion, sale and/or distribution of Amiodarone from this State throughout the United States.

FACTUAL BACKGROUND

98. All prescription drugs require approval by the FDA before the drug may be marketed for a specific designated use. Manufacturers of new drugs must submit a new drug application (hereinafter "NDA") to the FDA. An NDA must include information about the drug's safety and efficiency gleaned from clinical trials for a specific designated use.² It must also propose a label reflecting appropriate use, warnings, precautions, contraindications and adverse reactions.³ A drug can only be sold for its specific designated use; any other use requires manufacturers follow a specific protocol to do so.

99. For generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984. This statute amended the Food, Drug, and Cosmetic Act (hereinafter "FDCA") and is referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments provided an "abbreviated new drug application" (hereinafter "ANDA") procedure for generic manufacturers.⁴ Generic manufacturers are not required to repeat the clinical trials conducted by name brand manufacturers, assuming such trials were conducted.⁵ ANDAs are approved based on the

² 21 U.S.C. §355(a)-(b).

³ 21 C.F.R. §201.56.

⁴ 21 U.S.C. §355(j).

⁵ Although clinical trials were never completed by the brand manufacturer of Amiodarone, specifically for the use of Amiodarone for the treatment of A-fib.

initial safety profile of the name brand drug and are subject to all post-marketing events and post-sales events, including, but not limited to, collecting, tracking, and reporting adverse incident reports regarding the drug, and also are bound by the same obligations imposed on the original manufacturer in terms of complying with labeling obligations, reporting adverse events and only selling the drug for its specific authorized use.

100. Amiodarone, as the drug is commonly known, was developed in Belgium in the 1960s as a drug for treating a common heart condition known as angina. At that time, Amiodarone was released for marketing in most countries *other* than the United States.

101. In the 1970s, American physicians began obtaining Amiodarone from Canada and Europe for use in their patients with life-threatening arrhythmias who did not respond to other drugs. This activity was sanctioned by the FDA but only on a limited basis. By the mid-1980s literally tens of thousands of Americans were taking the drug without FDA approval or testing. Physicians in the United States apparently monitored the conditions of their patients more rigorously than their colleagues around the world, because they found the drug produced a bizarre series of side effects that other doctors seemed to have missed and that were not caught because of the lack of testing or randomized trials. After having supplied the drug for free to thousands of Americans for over five years, the FDA was essentially forced to release Amiodarone for marketing in the United States by the mid-1980's when foreign manufacturers of the drug threatened to cut off the supply to American patients.

102. In 1985, Wyeth received FDA approval⁶ to market and sell the anti-arrhythmic heart medication Cordarone® (Amiodarone hydrochloride is the generic formulation) under a special "needs" approval without the usually mandated rigorous and FDA-approved, double-blind randomized clinical trials. Although the FDA has expressly urged Wyeth and the generic manufacturers of this drug to conduct randomized clinical trials, especially if they intend to market Amiodarone for any of the other less serious

⁶ See NDA 18-972, Approval Letter, December 24, 1985.

arrhythmias and particularly on the targeted demographic of individuals over the age of 65, such trials have never been conducted. The FDA approval for Cordarone® thus remains a special and unusual “special needs” approval, as the customary and rigorous randomized clinical trials now required by the FDA for all new drug applications have never been conducted for Amiodarone. Wyeth was the initial manufacturer, promoter and distributor or “brand manufacturer” of Cordarone® in the United States, upon whose efforts the generic manufacturers, including Teva, piggybacked in terms of any testing (or lack thereof), warnings, and/or promotion of the drug.

103. Wyeth’s Cordarone® was approved by the FDA only as a drug of last resort for patients suffering from documented, recurrent, life-threatening, ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies. In essence, it was approved only for use in individuals facing probable death as their last hope for an efficacious treatment. It was never approved, even on a special needs basis, for the treatment of atrial fibrillation that Plaintiffs suffered from, as detailed above. In addition, the FDA required any person who was prescribed this medication was to first directly receive a “Medication Guide.”⁷ Distributing this Medication Guide to consumers was and is the responsibility of Defendants, not of any physician as they are not required to receive the Medication Guide.

104. Wyeth and others, including several generic manufacturers, aggressively and successfully marketed Cordarone® or its later initial bioequivalent Pacerone® for inappropriate “off-label” uses as a “first line anti-arrhythmic therapy.” Beginning in the late 1980s until the FDA warned and then ordered them to stop doing so as set forth below, Wyeth instituted and maintained an aggressive marketing plan positioning Amiodarone as a “first line anti-arrhythmic” via peer to peer events, articles in scholarly journals, and materials presented to physicians. These campaigns in many situations

⁷ Medication Guide for Amiodarone HCl. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf>.

focused on the use of the drug for atrial fibrillation, even though such general use was not approved by the FDA, and failed to warn prescribing physicians of the potential dangers associated with Amiodarone toxicity and dangers to atrial fibrillation patients. Wyeth's campaigns were so pervasive and effective that for an entire generation of physicians and in on-line fora that consumers reference as set forth above, the drug wrongfully became a first line therapy for atrial fibrillation because physicians and consumers were not warned of many of the potential dangers of the drug or that it had never been approved for such use by the FDA. Wyeth's fraudulent and misleading marketing campaigns resulted in repeated warning letters from the FDA to stop the false and misleading promotion of the drug, where such promotion downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy.⁸ The FDA letters noted that it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug.⁹ The purpose of this federal requirement is to protect patients by ensuring drug manufacturers test prospective uses of their drugs to randomized and well-controlled clinical trials to determine whether the drug is safe and effective for such specific designated uses. These requirements are meant to ensure that drug companies would give physicians and medical personnel trustworthy information so that medications are appropriately prescribed. That was not the case for Amiodarone and its use for the treatment of A-fib. Any specifically prescribed uses beyond those approved by the FDA are deemed "off-label" because they have not been approved by the FDA. While a pharmaceutical company is permitted to disseminate certain information about off-label uses, such dissemination must adhere to strict requirements. The manufacturer must submit an application to the FDA seeking approval of the drug for off-label use; the manufacturer must provide its marketing materials to the FDA before dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved

⁸ Warnings by the FDA to Wyeth began as early as 1988. <http://www.mcclatchydc.com/2003/11/04/28118/fda-oversight-of-off-label-drug.html>.

⁹ See 21 U.S.C. §§331(d), 352(f), and 355.

use of the drug, and, if the FDA deems it appropriate, “additional objective and scientifically sound information . . . necessary to provide objectivity and balance.”¹⁰ Neither Wyeth nor the Defendants such as Teva who were generic manufacturers and thus the beneficiaries of these promotional efforts, fully did so. This law also requires pharmaceutical companies to furnish federal regulators with advance copies of the information they disseminate.¹¹ Any deviation from these requirements violates FDA regulations. The dissemination of information in violation of these provisions also violates the FDCA.¹² Defendants took advantage of Wyeth's marketing plan positioning Amiodarone as a “first line anti-arrhythmic” described above, and directly benefited from the decades of marketing of the drug for “off-label” uses by Wyeth. The generic version of Amiodarone manufactured by Teva are also subject to the same advertising, marketing, and promotional requirements and restrictions set forth by the FDA for Wyeth in their advertising, marketing, and promotion of the drug Cordarone®. Defendants were able to take advantage of these promotional efforts in their sales of Amiodarone, focusing primarily on pricing in their marketing and promotional efforts to increase market share.

105. In connection with Defendants’ unlawful promotion and/or sale of Amiodarone not only as a treatment for atrial fibrillation, but also as a first-line treatment, they either directly or indirectly provided the indications and usage information regarding Amiodarone to the distributor of the Physician’s Desk Reference (“PDR”) and the developer of Epocrates, the two most widely used reference materials used by physicians in prescribing situations.

106. The PDR is an annual publication compiling product information about pharmaceuticals. Each year the PDR and its supplements are sent free of charge to licensed physicians in the United States and abroad. A typical entry includes the trade name and chemical name of the drug, a description of the drug, indications and

¹⁰ 21 U.S.C. §360aaa, *et seq.*

¹¹ 21 U.S.C. §360aaa.

¹² 21 U.S.C. §331(z).

contraindications for its use, warnings, adverse reactions, administration and dosage, and information on managing and adjusting the dosage of the drug. Likewise, Epocrates is a prescription drug reference source available online and via an application usable on smartphones and tablets, which likewise provides physicians with information about prescription drugs including uses, warnings, contraindications, dosage, etc. However, Epocrates provides this information for both brand name and generic drugs.

107. For many years, physicians relied upon the PDR book in prescribing situations to provide them with information about drugs available to treat certain conditions, indications and usages for drugs, as well as dosage information and contraindications. However, since at least 2010, the majority of physicians in the United States use the Epocrates application, which calls itself “[t]he #1 medical reference app,” in prescribing situations. The application, which is accessible on a smartphone or tablet, provides the prescribing physician with the same information about a particular condition or drug as the PDR. A 2014 article from *The New England Journal of Medicine* revealed that Epocrates tracks individual physicians’ search patterns, which are then used to send targeted “DocAlerts,” most of which are industry sponsored, which appear on the physicians’ tablet or smartphone screen within the application. Epocrates admits DocAlert is a marketing tool for pharmaceutical companies, noting “DocAlert messaging is an excellent way for pharmaceutical brand managers to target physicians at the point of care, by specialty.”

108. According to these reference materials, the information about prescription drugs that appears in Epocrates and the PDR comes from the manufacturers of the drug(s) as well as the FDA. The information is also supposed to be approved by the FDA. However, both the PDR and Epocrates contain misleading and incomplete information about Amiodarone, which deceives physicians into believing Amiodarone: (1) is approved for the treatment of A-fib when it never was; (2) was not approved solely as a drug of “last resort” for patients with ventricular fibrillation (“V-fib”) facing death; (3) provides benefits

to A-fib sufferers that outweigh the safety risks; and/or (4) underwent appropriate FDA-approved randomized, clinical trials, which it never did.

109. Defendants and other generic manufacturers of Amiodarone also are aware of the use of various other methods to unlawfully promote Amiodarone for unapproved uses including the use of Electronic Health Record companies such as Cerner, AthenaHealth, Epic, AllScripts, Practice Fusion and NextGen Healthcare, which provide generic manufacturers of Amiodarone a platform to reach physicians at the point of care in an attempt to promote Amiodarone and influence prescribing behavior.

110. Generic drug manufacturers also use a variety of internet-based tools to exert prescribing influence over physicians. This includes social networks specifically for healthcare providers like Sermo and Doximity where doctors can learn about new medical news and connect with other physicians. It also includes the creation of sponsored discussion forums to target doctors and identify key opinion leaders that can then be used to influence other physician's prescribing habits. These forums are used to solicit physician's opinions through surveys (paid and voluntary), recruitment of physicians for focus-groups.

111. Manufacturers of Amiodarone also provide false and/or misleading information to various reference sources used by physicians when contemplating prescribing a drug for an off-label use. This includes Wolters Kluwer's publications and applications, *Drug Facts and Comparisons* and *Off-Label Drug Facts*, which reports Amiodarone is an appropriate treatment for A-fib. As evidence of the success of this marketing and promotional campaign that Defendants were able to take advantage of and did nothing to correct, information about the use of Amiodarone as a treatment for A-fib has also been reported in a variety of sites used and visited by consumers, such as Web MD, the Mayo Clinic and even the American Heart Association, as well as retailer websites such as Wal-Mart.

112. Although people commonly understand a drug's "label" to refer to the sticker affixed to a prescription bottle, in this context the term "label" refers more broadly to the

written material that is sent to or accessed by the physician who prescribes the drug and the written material that comes or is supposed to come with the prescription bottle when the drug is handed to the patient at the pharmacy, such as the Medication Guide. 21 U.S.C. §321(m). These inserts contain detailed information about the drug's medical uses and health risks. 21 U.S.C. §355(b)(1)(F); 21 C.F.R. §201.57(a). Thus, the information about a particular drug in Epocrates or the PDR is also considered "labeling" under 21 U.S.C. §321(m) and as such cannot be false or misleading. The indications and usages of Amiodarone in both Epocrates and the PDR show the treatment of atrial fibrillation as an indicated use the drug, which is false and misleading as it has never been approved by the FDA for the treatment of atrial fibrillation. Teva licensed pictures of its Amiodarone pills to Epocrates for public display on the paid version of the application, failed to prohibit Epocrates from posting pictures of its pills on the Epocrates application or website and/or permitted such use.¹³ Defendants failed to request correction or ignored the false and misleading information in Epocrates and the PDR, thereby concealing the truth about Amiodarone to physicians who referenced those materials. Prescribing physicians were thus not adequately warned, because they received misleading "warnings" or information in addition to the FDA-approved labeling that watered down the FDA-approved labeling and rendered the overall warnings inadequate. The prescribing physicians identified above did not know that Amiodarone was not safe to prescribe for A-fib. Defendants thus did not take the steps reasonably necessary to bring that knowledge to the attention of the medical profession.

113. Defendant Teva, seeking to capitalize and being the beneficiary of the off-label marketing campaign initiated by Wyeth, received approval for the manufacture, marketing, sale and distribution of the generic formulation of Amiodarone.¹⁴ As it relied on the FDA filings of Wyeth, Teva would have sought and only obtained approval to

¹³ <https://online.epocrates.com/drugs/13409/amiodarone/Pill-Pictures>.

¹⁴ http://www.accessdata.fda.gov/drugsatfda_docs/applletter/1998/74739ltr.pdf

market Amiodarone only as a drug of last resort for the treatment of life-threatening, recurring ventricular fibrillation or tachycardia when other treatment options had failed, when it either knew or should have known that more than four out of every five Amiodarone prescriptions were for unapproved uses. As with all generic bioequivalent approvals, Defendants were required by the FDA to provide patients prescribed the drug with all FDA-approved labels, warnings and additionally, Medication Guides with information substantially similar to, if not exactly, as required from the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA.¹⁵

114. Correction or treatment of atrial fibrillation was never an FDA-approved use of Cordarone® or Amiodarone, either on a special needs basis or otherwise.¹⁶ Before being prescribed Amiodarone, each of the Plaintiffs who ingested Amiodarone were diagnosed with atrial fibrillation not deemed life threatening. None of these Plaintiffs were in a medical situation of “last resort” as to the management of their ventricular tachycardia, which was the only approved use of Amiodarone.

115. This off-label prescription and distribution of the drug to control a non-life threatening atrial fibrillation, which also is a direct result of the long-term promotional efforts of Wyeth and the continuing sales efforts of Defendants, and without the required Medication Guide, was a producing and proximate cause of Plaintiffs’ injuries.

116. The FDA has determined Amiodarone to be so dangerous that it requires the manufacturer to provide a direct warning to the patient, outside of the physician-patient relationship. Each manufacturer who ships a container of an FDA-approved drug product that also requires distribution of a Medication Guide is directly responsible for ensuring that Medication Guides are available in sufficient quantity for distribution to all patients with each prescription. Teva is a “manufacturer” as defined by the FDA. The FDA has recognized that it is important that patients directly receive appropriate risk information in the form of Medication Guides from the manufacturer in order to make informed

¹⁵ See 21 U.S.C. §355(j)(2)(A)(v); §355(j)(4)(G).

¹⁶ See Application 75-188 Approval Letter to Robert A. Fermia dated February 24, 1999.

decisions about certain prescribed medications. Indeed, the purpose of the Medication Guide is intended to specifically provide information directly to the patient outside of the physician-patient relationship for certain drugs “that the [FDA] determines pose a serious and significant public health concern.”¹⁷ The stated purpose of the Medication Guide is to directly provide the patient with safety information regarding the drug’s “serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect the patients’ decision to use ... the product.”¹⁸ The FDA has also mandated that the warnings included in the Medication Guides also go directly to the distributors and directly to the patient as an important notification distributed outside and in addition to any warning or information that is provided by the physician.¹⁹ Failure by Defendants to provide the Medication Guide and ensure its distribution in accordance with the requirements applicable to Defendants results in the distribution of a mislabeled drug, which is in violation of Delaware state law.

117. Under Delaware common and statutory law, for example Del. Code tit. 16, §3308, Teva’s failure to either disseminate or ensure that a pharmacy disseminate a drug without mandated warning results in a mislabeled or misbranded drug, which it is illegal for manufacturers such as Teva to distribute and/or sell. It is illegal for any person to manufacture, sell, deliver for sale, hold for sale or offer for sale of any drug, device or cosmetic that is adulterated or misbranded; any person to adulterate or misbrand any drug, device or cosmetic; and any person to receive in commerce any drug, device or cosmetic that is adulterated or misbranded, and to deliver or proffer delivery thereof for pay or otherwise. By not ensuring the provision of the Medication Guides, Teva either violated or aided and abetted the violation of these laws.

¹⁷ 21 C.F.R. §208.1(a)-(b)

¹⁸ 21 C.F.R. §208.1(c)

¹⁹ 21 C.F.R. §208.1(c); §208.24(c) (noting “[e]ach distributor or packer ... shall provide those Medication Guides, or means to produce Medication Guides, to each authorized dispenser to whom it ships a container of [amiodarone]”).

118. The serious side effects outlined in the Medication Guide, which Plaintiffs experienced in some way after taking Amiodarone as set forth above, included lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. Amiodarone causes additional horrific side effects, including causing blindness as it causes deposits to form on the cornea of the eyes. Amiodarone causes a very disfiguring blue-grey discoloration of the skin, generally in areas of exposure to the sun. Amiodarone often sensitizes the skin to sunlight so that even trivial exposure results in severe sunburns. Amiodarone causes hypothyroidism (low thyroidism). Some patients develop hyperthyroidism (high thyroidism), which is more dangerous and more difficult to treat. Amiodarone can cause kidney and liver toxicity, requiring liver enzymes to be periodically monitored. Amiodarone can cause severe gastric reflux, caused by a paralysis of the sphincter at the end of the esophagus.

119. The most serious side effect of Amiodarone, and the focus of the patient Medication Guide, is pulmonary toxicity/lung disease. Amiodarone produces two types of lung disease. The first is acute pulmonary syndrome, which looks and acts like typical pneumonia, with a sudden onset of cough and shortness of breath, a condition that improves once Amiodarone is stopped. The second type is more dangerous and life-threatening. This condition involves a gradual, almost unnoticeable, stiffening of the lungs that both the doctor and patient can overlook until finally severe irreversible lung damage has been done. This condition can occur quickly after taking the drug or can occur years after taking the drug. Lung toxicity has been found by the FDA to be in approximately 17%, or 1 in 5, patients taking the drug. Fatalities from pulmonary toxicity have been routinely reported to both Wyeth and other generic drug manufacturers, including Teva, that were not fully reported to the FDA, thus making them knowing participants in the conspiracy or concerted action to mislead users and/or prescribers of this drug. Because Plaintiffs were not provided a Medication Guide, they did not know, for example, that Amiodarone “should only be used in adults with life-threatening

heartbeat problems called ventricular arrhythmias” and even then when “other treatments did not work or were not tolerated.”²⁰ Plaintiffs did not know that any other use such as the use for supposed treatment of their A-fib was considered to be “off-label” and not approved by the FDA, or of the corresponding dangers associated with such uses.

120. The National Consumer Pharmacy Association has identified the failure of manufacturers to ensure the distribution of Medication Guides as a significant safety issue, and has called on the FDA to “enforce current FDA MedGuide regulations holding manufacturers accountable for providing Medication Guides in sufficient number or the means to produce Medication Guides in sufficient number, to permit the authorized dispenser to provide a Medication Guide to each patient who receives a prescription for the drug product.”²¹ Defendants are thus responsible for the consumer receiving the FDA-approved Medication Guide with each Amiodarone prescription. However, Defendants did not ensure that Medication Guides were provided in sufficient number to pharmacies to ensure each patient, including Plaintiffs, received such Guides along with prescriptions of Amiodarone.

121. Because their pharmacists were not provided a Medication Guide in sufficient quantity to give directly to them as required by FDA regulations, Plaintiffs did not know “the medicine stays in your body for months after treatment is stopped.”²² The effects of Amiodarone are extremely long lasting. Amiodarone is fat-soluble, and tends to concentrate in tissues including fat, muscle, liver, lungs, and skin. It confers a high volume of distribution and a long half-life (the amount of time it takes for one-half of an administered drug to be lost through biological processes such as metabolism and elimination). Amiodarone has also been determined to affect many different organs in many ways. First, the drug takes many weeks to achieve the maximum effectiveness.

²⁰ Medication Guide for Amiodarone HCl. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf>.

²¹ Use of Medication Guides to Distribute Drug Risk Information to Patients, Colleen Brennan, R.Ph; Bryan Ziegler, Pharm. D., MBA.

²² Medication Guide for Amiodarone HCl. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf>.

Amiodarone is literally “stored” in most of the tissues of the body and as a result, to “load” the body with the drug all the tissues need to be saturated. Therefore, the typical loading regimen of Amiodarone is to use extremely large dosages of the drug for the first week to two weeks, then to taper the dosage over the next month. It is not unusual to give a patient 1200 to 1600 mg a day when starting the drug and to maintain the patient on 100 to 200 mg per day on a chronic basis. Amiodarone also leaves the body very slowly. The drug is not excreted like most drugs through the liver or kidney but is only lost when Amiodarone-containing cells such as skin cells or cells from the GI tract are lost. Therefore, even when it is decided that the patient needs to stop taking Amiodarone the drug remains in the system in measurable quantities for months and even years.

122. Because the drug is stored in many different types of tissues it can cause side effects that affect many different types of organs. And because of its long half-life, Amiodarone’s dangerous properties continue to cause injuries in patients such as Plaintiffs long after they ceased using the drug, and even after they have been diagnosed with particular issues, including serious pulmonary injuries. Thus, a Plaintiff could be diagnosed with pulmonary issues but not be aware it is associated with Amiodarone use for months if not years after that diagnosis. This information was unknown to Plaintiffs due to the failure of the Defendants to provide the Medication Guide and otherwise provide adequate warnings to Plaintiffs, an illegal act that has been continuous and on-going.

123. The need for the Medication Guide was so great the FDA not only replaced package inserts, but “all” other direct means of providing information to consumers of the dangers of the drug, which would include relying solely on warnings from physicians. According to the FDA, the Medication Guide replaces the previous “package inserts” or any other means by which the manufacturers may attempt to directly warn consumers of the effects of the drugs Cordarone® or Amiodarone. Without distributing these guides or otherwise providing adequate warnings, these drugs are “mislabeled,” “misbranded,” “adulterated” and illegally sold under Delaware state law. Strict liability is imposed on

the sellers of “mislabeled,” “misbranded,” “adulterated” and illegal drugs. This is a “non-delegable” duty that cannot be accomplished by other means. Defendants refused to ensure the required Medication Guide was disseminated and provided to every consumer prescribed this drug, which was a pre-condition of the sale of this drug to consumers, including Plaintiffs.

Plaintiffs’ Use of Amiodarone and Resulting Injuries

124. As a result of Defendants’ illegal, off-label promotion and distribution of Amiodarone as a viable treatment for atrial fibrillation without the required Medication Guide or other adequate warnings and as a “first line” arrhythmia drug, Plaintiffs and Plaintiffs’ physicians were unaware that they would be exposed to the risks of pulmonary fibrosis and other injuries.

125. As a result of the information concealed by Defendants and the half-life of Amiodarone as set forth above, the link between Plaintiffs’ injuries and Defendants’ wrongful conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statutes of limitation for filing Plaintiffs’ claims. Even a diagnosis of pulmonary toxicity would not necessarily lead someone to believe it was due to the use of Amiodarone, particularly because of the parallels between that diagnosis and pneumonia.

126. A lay person exercising reasonable diligence could not have discovered, among other things, that (1) Amiodarone was not FDA-approved for the treatment of atrial fibrillation and they took the drug on an “off-label” basis; (2) by law he or she was supposed to receive the Medication Guide with the prescription of Amiodarone; and (3) that Amiodarone-induced pulmonary fibrosis is not an extremely rare side effect of Amiodarone use but rather sufficiently common that the FDA requires Defendants to warn physicians and users of this risk. Such a discovery would require a complex examination and analysis of various legal statutes and regulations, which is far beyond the knowledge or ability of a lay person.

127. For the reasons detailed below, the running of any applicable statute of limitations is also tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to their conspiracy with companies such as Wyeth to conceal the true facts detailed herein through the use of affirmative misrepresentations and omissions of material fact from Plaintiffs and Plaintiffs' physicians of the true risks associated with Amiodarone and the failure to ensure distribution of the Medication Guides in the form and manner required by law. It was Defendants' failure to provide both the Medication Guide and adequate warnings to Plaintiffs in the form and manner required by law, which would have provided Plaintiffs with information about the serious complications associated with Amiodarone, which requires the statute of limitations to be tolled. If Defendants had provided Plaintiffs with the Medication Guide or other adequate warnings, as required by law, Plaintiffs would more likely to have been on notice as to the serious complications associated with Amiodarone. It would be inequitable to allow Defendants to assert a statute of limitations defense when their acts of concealment prevented Plaintiffs from learning the truth about Amiodarone. It was as a result of Defendants' acts of concealment that Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence, that Plaintiffs had been exposed to the risks alleged herein and that those injuries were the direct and proximate result of the wrongful acts and omissions of material facts by Defendants.

128. At all materials times, despite FDA warnings and thousands of adverse patient experiences, Defendants continued their marketing, promotional, and sales practices beginning from at least 1999 as set forth above through the present date, and have continued in their acts of conspiracy as detailed above. Thus, despite the repeated changing of the warnings and labeling multiple times over the past 25 years and the requirement for the distribution of Medication Guides to all patients as set forth below, and knowing of numerous catastrophic injuries caused by both Cordarone® and Amiodarone, Defendants continued to actively conceal and understate the drug's nature and adverse risks of catastrophic injury, pulmonary injury and death despite their duty to

disclose such information and the need to distribute and ensure distribution of the Medication Guides, thereby tolling any applicable statutes of limitation.

A. Cordarone®, Concealment, and the Off-Label Promotional Scheme That Created the Duty to Disclose Material Facts to Plaintiffs

129. As noted above, on or about December 24, 1985, Wyeth introduced Cordarone® into the United States' stream of commerce. Wyeth received approval for Cordarone® from the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia, and further, only when these conditions would not respond to other available anti-arrhythmic drugs and therapies and later was accompanied by a Medication Guide or other appropriate warning.

130. The FDA's early specific enforcement actions regarding the marketing and labeling of the drug Cordarone®, include:

- a. On or about October 7, 1986: label revision;
- b. On or about May 15, 1987: label revision;
- c. On or about August 7, 1987: package change;
- d. On or about October 28, 1987: manufacturing changes;
- e. On or about June 29, 1988: label revision;
- f. On or about September 14, 1988: label revision;
- g. On or about December 13, 1988: package change;
- h. On or about February 2, 1989: label revision;
- i. On or about July 28, 1989: formulation revision;
- j. On or about August 9, 1990: label revision;
- k. On or about August 9, 1990: manufacturing change;
- l. On or about April 14, 1994: label revision;
- m. On or about October 15, 1995: label revision;
- n. On or about June 15, 1998: label revision;

- o. On or about January 5, 1999: label revision;
- p. On or about October 8, 1999: label revision;
- q. On or about December 18, 1999: label revision;
- r. On or about September 20, 2002: control supplement;
- s. On or about December 18, 2002: label revision;
- t. On or about April 30, 2003: label revision;
- u. On or about May 6, 2003: label revision; and
- v. On or about May 21, 2004: label revision.

131. On or about December 15, 1989, and subsequently in 1992, 1998, and thereafter, the FDA sent violation communications to Wyeth regarding the FDA's determination that Wyeth had violated the FDCA and its implementing regulation by, *inter alia*, disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Cordarone®. In so doing Wyeth misrepresented Cordarone's® indications and usage, efficacy, risks, and benefits. Further, Wyeth failed to submit marketing materials to the FDA, in violation of the FDCA.

132. In May of 1995, the Australian Government's Therapeutic Goods Administration ("TGA") (that country's counterpart to the FDA) issued an Australian Adverse Drug Reactions Bulletin, emphasizing that Amiodarone was appropriate only for use in the treatment of ventricular and supraventricular arrhythmias. Notably, this Bulletin highlighted that "the drug [Amiodarone] is known to have multiple adverse effects, which can involve most organ systems," and again stressed that "Amiodarone is only to be used in patients with serious arrhythmias where there is no safer drug therapy." Defendants either were or reasonably should have been aware of this finding and thus any off-label promotion of Amiodarone for the treatment of A-fib, particularly without the required warnings, was improper and unsafe for patients.

133. On or about April 29, 1996, the FDA required Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

- a. Carcinogenesis;
- b. Mutagenesis;
- c. Impairment of fertility, pregnancy; and
- d. Neonatal hypo- or hyperthyroidism.

134. The severity of catastrophic adverse reactions, including death, led Wyeth to discontinue production and distribution of Cordarone® in Canada on or about September 10, 1996.

135. On or about February 11, 1997, the FDA issued a warning letter to Wyeth regarding Cordarone's® understated or incorrect labeling and warnings based on the FDA's medical research. Thereafter, on or about April 16, 1997, Wyeth changed its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

- a. Loss of vision;
- b. Impairment of vision, including optic neuritis, optic neuropathy, corneal lesions, lens opacities, optic disk damage, papilledema, retinal hemorrhage and degeneration, photophobia;
- c. Liver injury;
- d. Pregnancy;
- e. Adult Respiratory Distress Syndrome;
- f. Angioedema; and
- g. Mortality.

136. In 1998, the FDA issued a Written Request for Pediatric Studies under Section 505A of the Act to Wyeth regarding Cordarone®. The apparent basis for this request was that insufficient tests, surveys, and studies had been conducted regarding Cordarone® consumption by pediatric patients, although there was knowledge by

Defendants and other drug manufacturers and in the medical community that off-label use of Cordarone® in pediatric patients was becoming more and more common.

137. Also, in 1998, the FDA issued a letter to Wyeth requiring that company to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

- a. Mortality (based upon the European Infarct Amiodarone Trial and Canadian Myocardial Infarct Trial);
- b. Precautions regarding volatile anesthetic agents for Amiodarone users undergoing surgery;
- c. Carcinogenesis;
- d. Mutagenesis;
- e. Impairment of fertility, pregnancy; and
- f. Neonatal hypo- or hyperthyroidism.

138. On or about December 6-10, 1998, Wyeth sponsored a Continuing Medical Education (“CME”) for the 33rd Midyear Clinical Meeting of the American Society of Health-System Pharmacists. This CME was for healthcare providers, including pharmacists, as part of Defendant’s ongoing promotion of Cordarone® for off-label purposes. As part of the CME, Wyeth produced and distributed to attendees a 68-page official looking, “peer review appearing” magazine, “The Pharmacist Reporter (July 1999, Vol. 4, No. 5).” This publication was actually a promotional bulletin highlighting Wyeth’s goal for Cordarone®: increased off-label use. Among the topics addressed in various articles in “The Pharmacist Reporter,” several of which appear to soften, downplay, and/or minimize Cordarone’s® devastating side effects, were the following:

- a. “An Aggressive Treatment Strategy for Atrial Fibrillation”;
- b. “Use of Amiodarone in Patients Undergoing Cardiothoracic Surgery”; and
- c. “A Possible New Standard of Care for Prehospital Cardiac Arrest.”

In fact, they marketed, promoted, and “pushed” Amiodarone, not as a drug of last resort, but as a drug suitable as an initial therapy and to treat non-life-threatening heart conditions such as A-fib. by (1) authoring, directly and indirectly, various studies and articles touting Amiodarone as a treatment for A-fib; (2) sponsoring or funding various Continuing Medical Education (CME) events attended by prescribing physicians which

included providing misleading and false materials to attendees; (3) providing false and misleading information to the publishers, developers and distributors of reference materials, such as the PDR and Epocrates and other compendia, used by physicians in prescribing situations; (4) causing representatives to visit prescribing physicians; (5) placing misleading information on websites and catalogs; (6) sponsoring trials, studies or surveys purporting to show Amiodarone as a treatment for A-fib; and/or (7) paying influential cardiologists to act as “opinion leaders” advocating the off-label use of Amiodarone.

139. On or about October 8, 1999, the FDA issued a letter to Wyeth requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

- a. Clinical pharmacology and pharmacokinetics, in that food consumption increases Cordarone’s® absorption rate;
- b. Geriatric use, whereby clinical studies of Cordarone® in persons 65 and older had not been conducted; and
- c. Dosage and administration, in that food consumption must be addressed in dosing and loading doses are to be used.

140. On or about January 12, 1999, the FDA issued a letter to Wyeth requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding geriatric use, because clinical studies of Amiodarone in persons 65 and older – the primary demographic for Amiodarone use -- had not been conducted.

141. On or about February 12, 1999, the FDA issued a letter to Wyeth requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the effects of food consumption on dosage and administration.

142. In February of 2002, the Australian TGA issued an Australian Adverse Drug Reactions Bulletin, alerting healthcare professionals in that country that numerous adverse medical events associated with Cordarone® had been reported to the TGA in 2002 and 2001, including Cordarone® induced pulmonary toxicity and deaths. The TGA

warning contained the following important information for healthcare professionals, which were never shared by Defendants with healthcare professionals in the United States:

“Although commonly insidious in onset, Amiodarone—induced pulmonary toxicity may develop rapidly. The lowest effective dose should be used, and patients should be instructed to report any dyspnea or non-productive cough. Amiodarone also has other toxicities including hepatotoxicity which can cause cirrhosis and hepatic failure, cardiovascular effects including bradycardia and tachycardia, skin reactions including photosensitivity and discoloration, neurotoxicity including ataxia and peripheral neuropathy, as well as both corneal deposits and hyper- and hypothyroidism.”

143. On or about December 18, 2002, the FDA issued a letter to Wyeth requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®, specifically adding new warnings or revising minimalist warnings regarding adverse drug interactions with immunosuppressant static drugs, resulting in rhabdomyolysis.

144. On or about December 19, 2002, the FDA issued a warning letter to Wyeth requiring Wyeth to correct understated warnings and/or issue new warnings regarding the following:

- a. Acute onset (days to weeks) of pulmonary toxicity;
- b. Patients having preexisting pulmonary disease have poorer prognosis if pulmonary toxicity develops; and
- c. Post-marketing reports include possible fatal respiratory disorders (including distress, failure, arrest, ARDS, fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, and pulmonary infiltrates).

145. In 2003, the FDA issued a warning letter to Wyeth, requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®, specifically, adding new warnings or revising minimalist warnings regarding the following:

- a. worsened arrhythmia;
- b. thyroid abnormalities;
- c. drug interactions (protease inhibitors, histamine antagonists, immunosuppressives, antibiotics, cardiovasculars, anti-arrhythmics, anti-hypertensives, anticoagulants);
- d. other substance (grapefruit juice, herbal supplements) interactions;
- e. electrolyte disturbances; and
- f. nursing mothers passing the drug to newborns through breast milk.

146. In 2003, the FDA sent violation communications to Wyeth regarding the FDA’s determination that it had violated the FDCA and its implementing regulation by, *inter*

alia, disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Cordarone® by children and pregnant women. Thereafter, Wyeth notified physicians to stop prescribing Cordarone® to children and pregnant women because of the serious risk of permanent injuries.

147. Wyeth, and thus also Teva, was on notice, by no later than 1998, that severe damage to the lungs were side effects of the ingestion of Cordarone®, which can cause permanent injury and death.

148. Wyeth, and thus also Teva, has consistently failed to disclose and misrepresented to physicians Cordarone's® indications and usage, efficacy, risks, and benefits. Wyeth and thus also Teva failed and refused to actively and affirmatively monitor Cordarone's® and Amiodarone's "off-label" unapproved uses insofar that such uses caused catastrophic injuries and death. Wyeth, however, continued to promote Cordarone® for unapproved uses, which ultimately had direct beneficial results for Teva as well in terms of creating the impression Amiodarone could properly be used for the treatment of atrial fibrillation.

B. Defendants' Awareness of the Illegal Promotion of Amiodarone

149. At all material times, Defendants have had actual or constructive knowledge that Amiodarone causes and contributes to severe and disabling medical conditions such as experienced by Plaintiffs as set forth above, which include, without limitation, the following: pulmonary toxicity, pulmonary fibrosis, hepatic kidney damage and failure, neurotoxicity, neonatal hypothyroidism, birth defects, optic neuritis, toxic optic neuropathy, blindness, peripheral neuropathy, heart damage and failure, hypotension, serious exacerbation of arrhythmias, and congestive heart failure. Defendants have also either directly or indirectly received information concerning cases of these severe medical conditions resulting from the use of Amiodarone such as those experienced by Plaintiffs.

150. Defendants have received information concerning more than one thousand deaths resulting from the use of Amiodarone.

151. Defendants have concealed information about catastrophic injuries and death attributable to this drug, and thousands of serious adverse medical events in their exclusive possession from the FDA, health care professionals, and consumers, including Plaintiffs. There are millions of persons who are diagnosed with A-fib annually. Amiodarone over the years has become the number one prescribed drug for the treatment of A-fib. Based on the percentages of persons diagnosed just with pulmonary toxicity, there would be tens of thousands of adverse event reports submitted each year. Yet that does not appear to be even close to the number of these reports submitted to the FDA in connection with Amiodarone.

152. Healthcare providers as well as patient-consumers reported these events directly to companies such as Teva. Yet none of these companies publicly distributed this information

153. In addition to these direct notices of adverse events, the FDA had, and continues to have, in effect an adverse reaction surveillance system for all regulated drugs, including Amiodarone, called the Adverse Event Reporting System (“AERS”).

154. AERS has placed Defendants on notice of numerous instances of catastrophic injuries caused by ingestion of Amiodarone.

155. At all material times, Defendants failed to disclose to the FDA, healthcare professionals, consumers, and Plaintiffs the specific material adverse information they possessed concerning the number of incidents and actual adverse medical events, injuries, and deaths suffered by Amiodarone users.

156. Data on the FDA’s FAERS database bear this out. The number of AERs reported has increased significantly in the last few years for Amiodarone, correlating to the litigation surrounding Amiodarone which began in 2015. In 2014, there were 1,328 adverse events reported, with 1,228 of these being serious cases, including 241 deaths. In

2018, the last full year of reports, 3,596 adverse events were reported with 3,449 of these being serious cases, including 558 deaths—a 270% increase since 2014. This indicates either underreporting of AERs in the years before the Amiodarone litigation or that there has been a three-fold increase in the number of Amiodarone prescriptions between 2014 and 2018. There is no indication that in this short four-year span the number of Amiodarone prescriptions suddenly increased almost three-fold.

157. Instead, Defendants actively concealed such facts and either actively promoted, or piggy-backed on the promotional efforts of innovator brand drug manufacturer Wyeth, for “off-label” unapproved uses as described herein through various means, including, but not limited to, the following:

- a. Direct-to-physician and direct-to-pharmacist promotion through sales representatives;
- b. Promotion through funding and manipulation of so-called “educators” who organize and arrange CME courses for physicians and pharmacists;
- c. Formulation of unlawful conspiracies with certain medical marketing and medical “education” entities to promote – without appearing to promote – such off-label uses;
- d. Sponsorship and funding of the production of CME materials;
- e. Cultivation and development of so-called “opinion leaders” in local medical communities and support for the careers and research of those physicians, pharmacists, and researchers who advocate off-label uses;
- f. Sponsorship of journal supplements and symposia on off-label uses for Cordarone®;
- g. Placing (through sponsorship of limited trials, studies, and surveys) of medical literature databases showing positive effects (already established) on risk factors with the twin purposes of overwhelming any independent study showing negative effects on different risk factors, and causing earnest but time-crunched physicians to be impressed with the sheer quantity of favorable (but redundant) studies on MedLine, or medical library, search;
- h. Media advertisements and brochures, some of which were disguised as “educational materials”; and
- i. Various other forms of marketing and promotion including websites and catalogs promoting Amiodarone.

158. In accepting the benefits of brand innovator Wyeth's efforts in promoting "off-label" uses of Cordarone®, Defendants would sometimes escape disclosure for any role at all in the presentation of their desired view. At other times, Defendants would be disclosed merely as having provided an "unrestricted educational grant" for seminars, when in fact the grant was premised on an understanding about the content, or Defendants otherwise exercised influence over it.

159. Additionally, pharmaceutical sales representatives utilized materials and sources during this time period to promote the generic Amiodarone in the stream of commerce for the "off-label" uses promoted by Defendant Wyeth.

160. Defendants were required under the law to ensure the Medication Guide was provided to all patients prescribed Amiodarone. Despite this duty to provide material information to consumers such as Plaintiffs, Defendants failed to do so.

161. At all material times, the Amiodarone manufactured, distributed and/or supplied by Defendants to Plaintiffs was and is unaccompanied by proper warnings regarding all possible adverse side effects and the comparative severity and duration of such adverse effects, including, but not limited to, through the required Medication Guides. The warnings generally given by them did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of these side effects, particularly with regard to "off-label" use.

162. At all material times, Defendants failed to warn the public and Plaintiffs of material facts regarding the safety and efficacy of Amiodarone, such that this drug would likely have never been approved, and no physician would have been able to prescribe this drug but only for the most limited and extreme use in the United States.

163. Based on the thousands of complaints it has likely received, adequate testing would have shown that Amiodarone possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope, and severity should have been made with respect to the use of Amiodarone, particularly for "off-label" use.

164. For example, although Defendants should have known, and currently know that the majority of patients consuming Amiodarone are older, including many of those aged 65 and over that are Plaintiffs, Defendants failed and refused to conduct testing, studies, surveys, and/or report results regarding Amiodarone use in this age group, particularly those diagnosed with A-fib. The warnings provided by Defendants fail to note this material fact.

165. At all material times, the Amiodarone manufactured, distributed, and/or supplied by Defendants was defective due to inadequate post-marketing warning and instruction. Once Defendants knew or should have known of the risk of injury from Amiodarone, especially for “off-label” use, Defendants failed to provide adequate and required warnings to physicians, users or consumers of Amiodarone, including the Plaintiffs.

166. At all material times, while Defendants concealed this adverse event information, Defendants at least by aggressive pricing illegally promoted Amiodarone for uses never authorized by the FDA. At all times material, Defendants also promoted Amiodarone for heart conditions less severe than life-threatening ventricular arrhythmia (the only purpose for which the drug originally received FDA approval). Defendants engaged in a conspiracy of silence with the companies identified above regarding “off-label” use, choosing to market, distribute and/or promote the drug for “off-label” use, and then feigning ignorance before the FDA, health care providers, and consumers, and failing to ensure distribution of the Medication Guides, all of which continues to date.

167. Defendants also failed and refused to conduct thorough testing on Amiodarone’s side effects, despite knowing that their scheme to promote the drug for “off-label” uses had been, and continues to be, successful. As a result, Defendants did not fully inform or provide the FDA with all required information or any complete analyses of these material side effects and contraindications, despite specific warnings that had been provided to Wyeth regarding the inadequacy of the testing of Amiodarone for the treatment of A-fib and for use in individuals older than 65, or that would have justified the use of Amiodarone for the treatment of A-fib or sought approval from the FDA to do so.

168. The FDA did not prohibit Defendants from making any changes in the labeling for Amiodarone, or in the information provided to physicians, or from requiring the distribution of the Medication Guides. Nor is there any indication that the FDA in any formal proceedings would not have approved any changes that would have made it clear to both consumers and physicians that Amiodarone was never approved or to be used for the treatment of A-fib. As a result, it was not impossible for Defendants to comply with both their legal duties under Delaware common law and other statutory obligations under Delaware law to provide sufficient warnings regarding the significant risks associated with the use of Amiodarone for the treatment of A-fib, particularly for people over the age of 65, and comply with any FDA requirements, particularly with regard to the dissemination of the Medication Guide.

169. Under increased FDA scrutiny and mandates, Defendants have been forced to correct and change their warning labels, and add new warnings, for adverse side effects about which they knew long before being required to make such changes.

170. At all material times, Defendants' direct or indirect participation and involvement in the deception, concealment, and illegal marketing and promotion described in this Complaint has been so pervasive throughout the United States that nationwide publications, prescribing physicians and consumer patients have during the relevant time period still believe that Amiodarone is an acceptable initial, secondary, or otherwise early-stage anti-arrhythmic intervention. This deceptive marketing served (and continues to serve) Defendants in several ways, including: (1) instilling Defendants' desired view about the drug's "off-label" uses among health care providers; (2) by concealing their involvement in these activities, they would escape the legal ramifications of their unlawful promotional activities; and (3) boosting Defendants' profits for the drug.

171. At all material times, Defendants owed a duty to the health care providers, consumer patients, and Plaintiffs to engage in honest and non-deceptive practices; exercise due care under the circumstances, to exercise due care in the design, manufacture, marketing, promotion, sale, and/or distribution of Amiodarone and the

required Medication Guide in the manner required by law; to provide a reasonably safe and non-defective drug; to provide adequate and appropriate warnings for said drug; to comply with federal guidelines, rules, and regulations; and/or to sell and distribute the drug in accordance with FDA regulations.

172. While it is not unlawful for a physician to prescribe a drug for an unapproved use, it is unlawful for the manufacturer of the drug to promote or market the drug for a dangerous unapproved use. The reasoning is simple -- while FDA approved drugs must undergo clinical trials to show they are safe and efficacious for the intended use(s), no such testing would have occurred for unapproved uses. Indeed, a 2006 study found that 73% of medications prescribed for off-label purposes had no or poor scientific support.²³ This same study found that off-label use results in a much higher incidence of medication errors, finding that 77% of such reported errors involved off-label prescriptions. Here, that risk is exponentially compounded due to the fact Amiodarone never even underwent randomized clinical trials to show safety and efficacy for its only approved use. This is the reason it was only approved for this narrow, limited purpose as a drug of last resort for individuals who have exhausted all other treatment options for a potentially lethal arrhythmia, such as ventricular fibrillation and ventricular tachycardia.

173. At all material times, Defendants either directly or indirectly marketed, distributed and/or sold Amiodarone as having approval, characteristics, uses, and benefits that the drug did not have, and as being legal to sell for its “off-label” use when it was not.

174. At all material times, Defendants did design, create, test, develop, label, sterilize, package, manufacture, market, promote, advertise, distribute, sell, and/or otherwise cause the product to be placed into the stream of commerce, ultimately to be ingested by Plaintiffs.

²³ Radley D.C., Finkelstein S.N., Stafford R.S. Off-label prescribing among office-based physicians. Arch Intern Med. 2006;166(9):1021–1026.

175. At all material times, Defendants either directly or indirectly failed and refused to actively and affirmatively monitor Amiodarone's "off-label," unapproved uses insofar that such uses caused catastrophic injuries and death. Defendants, however, continued to illegally market, distribute and/or sell Amiodarone for unapproved uses.

176. At all material times, Defendants engaged in a continuing course of misstatements, illegal conduct, concealment and/or non-disclosure of material facts that prevented Plaintiffs from knowing or having reason to know of the scope of Defendants' illegal misconduct. This includes, but is not limited to, the Defendants' obligations to ensure a Medication Guide in compliance with FDA regulations is received by a Plaintiff's dispensing pharmacy and ultimately by each Plaintiff. Each link in distribution must ensure compliance with the Medication Guide, which requires coordination by Defendants with the other steps in the distribution chain.

C. Amiodarone Did Not Undergo the Rigorous FDA Approval Process Required for Federal Preemption

177. As noted above, on or about December 24, 1985, Wyeth introduced Cordarone® into the United States' stream of commerce. Wyeth received approval for Cordarone® from the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; further, only when these conditions would not respond to other available anti-arrhythmic drugs and therapies and only if provided along with the required Medication Guide. Furthermore, despite repeated requests by the FDA at the outset of the review process and throughout the history of the drug, neither Wyeth nor any other manufacturer of this drug, including Teva, have submitted this drug to the rigorous randomized clinical trials required for FDA drug approval.

178. Unlike any other drug in modern history, Amiodarone became widely used without rigorous, FDA sanctioned randomized clinical trials. The legal reasons for preemption applied to certain drug litigation for FDA-approved drugs are not present

with Amiodarone because Amiodarone has never been subjected to double blind testing as mandated by the FDA, and its use for treatment of A-fib is not permitted by the FDA.

179. Amiodarone never underwent the rigorous clinical randomized trials all other FDA-approved drugs, other than a few “grandfathered” drugs with long market histories, have undergone. Despite repeated requests, demands and even threats from the FDA, the manufacturers of Amiodarone and its FDA labeled “brand-names,” including Wyeth’s Cordarone®, have never undergone the type of clinical trials that would show its defects or the benefits verses the risks associated with the drug’s use. Despite the economic argument that the patent has expired, or that the costs of testing is too high to justify the investment, Amiodarone continues to generate enormous revenues and profits for companies such as Teva without the public having the protection of FDA randomized clinical trials.

180. The only trials Amiodarone underwent were non-scientific, reporting a combination of various patient results to obtain statistical data that is neither randomized nor reliable, and which interestingly enough did not even provide the statistical data that has been determined by the FDA to be accurate for the drug and required in the black box labeling of the product. This combination of reporting of various patient results was non-scientific and cannot serve as the basis for a claim of preemption.

181. Without rigorous, scientific, clinical trials and randomized testing approved by the FDA, the reasons for FDA preemption do not exist and cannot be sustained. Neither the so-called “brand names” nor the generic versions of this drug offer any protection to the public in terms of drug undergoing review through the rigorous FDA approval process. Since the manufacturers will not undergo FDA-approved testing they cannot use the FDA approval process as a shield from liability when sued. None of the reasons articulated by the United States Supreme Court for the protection preemption provides are present with Amiodarone. None of the cost-benefit analysis is present. In addition, none of the regulatory analysis argument and thus no argument about the need to protect “federalism” is present to support preemption.

182. This is not to say the FDA completely disregarded its regulatory or enforcement powers regarding Amiodarone. While no testing that would justify preemption was ever performed, when the significant evidence of the dangers of Amiodarone and its many side effects became known, the FDA repeatedly amended the labeling requirements for Amiodarone, mostly resulting from public pressure, and enacted a requirement that the drug manufacturers directly provide the patient a FDA-approved Medication Guide by ensuring distribution of the Medication Guides to the patients along with the drug. Due to the failure to conduct required randomized clinical testing by the Defendants, Plaintiffs' claims are not preempted from claiming Defendants illegally marketed the product for off-label use, and Plaintiffs are not preempted from claiming that the product itself is unreasonably dangerous as it was packaged, marketed, designed, manufactured and sold. Most importantly, Plaintiffs are not preempted from claiming Defendants failed to warn of the dangers of the product by failing to ensure the required Medication Guide that consisted of language the FDA approved was disseminated directly to consumers such as Plaintiffs in the form required by law. This action is not inconsistent with that requirement, and in fact is consistent with it based on Defendants' failures to, *inter alia*, ensure the Medications Guides were timely provided to Plaintiffs.

183. The failure to provide the FDA Medication Guide in the manner required by law is a different claim than merely alleging the package insert or labeling fails to inform or warn patients or consumers of the dangers of the product. The failure to provide each patient a Medication Guide by failing to provide the Medication Guides to the distributor in proper form or in sufficient quantity, if at all, or to ensure the Medication Guide is provided to the pharmacists and patients in proper form if at all, is a direct violation of the FDA's mandate intended to warn patients directly outside the communication with the prescribing physician and the state duty to adequately warn the consumer in the absence of a sufficient warning to physicians.

FIRST CAUSE OF ACTION

(Strict Products Liability – Failure to Warn)

184. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further allege as follows.

185. At all times relevant to this action, Defendants engaged in the business of designing, manufacturing, testing, marketing, labeling, causing to be distributed and/or otherwise placing into the stream of commerce Amiodarone for sale to, and use by, members of the public, including Plaintiffs who took the drug.

186. Amiodarone posed increased risks of harm and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after the time of the manufacture, distribution, and sale of Amiodarone. Defendants knew or should have known of the defective condition, characteristics, and risks associated with said product, for the reasons set forth herein. Defendants disregarded this increased risk of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with increased risk of harm by failing to ensure the Medication Guide was provided to Plaintiffs; unlawfully concealing from Plaintiffs and their prescribing physicians the dangerous problems associated with Amiodarone, including that it was not FDA approved for the treatment of A-fib, has not undergone any randomized, clinical trials for safety, and was only approved by the FDA as a drug of last resort for individuals with deadly V-fib.

187. The Amiodarone that was manufactured, distributed, and/or sold by Defendants to Plaintiffs was in a defective condition that was unreasonably and substantially dangerous to any users or ordinary consumers of the device, such as Plaintiffs. Such ordinary consumers, including Plaintiffs, would not and could not have recognized or discovered the potential risks and side effects of Amiodarone as set forth herein based on the lack of information provided to them that Defendants were required to ensure they directly received.

188. The warnings and directions provided with Amiodarone by Defendants failed to adequately warn of the potential risks and side effects of Amiodarone and the dangerous propensities of this medication, which risks were known or were reasonably scientifically

knowable to Defendants, when they failed to provide proper warnings. Specifically, Defendants failed to ensure the Medication Guide was provided to all consumers, including Plaintiffs, in the manner required by law; and concealed from Plaintiffs and their prescribing physicians, the true risks and complications of Amiodarone including that it was not FDA-approved for the treatment of A-fib, has not undergone any randomized, clinical trials for safety, and was only approved by the FDA as a drug of last resort for individuals with deadly V-fib.

189. Defendants' failure to ensure the Medication Guide was provided to Plaintiffs, along with the concealment of material facts to Plaintiffs and their prescribing physicians, were a substantial factor in causing Plaintiffs' injuries, losses and damages, as described herein. Further, the prescribing physicians read and relied on the PDR, Epocrates app or other prescribing reference source in prescribing Amiodarone to Plaintiffs. Teva either was or should have been aware of the statements made in those materials since, for example, Teva permitted use of pictures of its own Amiodarone pills on the Epocrates app and was under a duty to correct these materials as a form of labelling. If the information contained in the PDR, Epocrates or other reference sources had been truthful and not concealed material information, the prescribing physicians would not have prescribed Amiodarone to treat Plaintiffs' A-fib.

190. Defendants also failed to report thousands of serious adverse medical events in their exclusive possession to the FDA, health care professionals, and consumers, including Plaintiffs.

191. In addition to these direct notices of adverse events, the FDA requires the use of AERS. Defendants failed to report all serious injuries related to Amiodarone use to AERS.

192. The accurate reporting of such adverse events is critical to the safe and effective use of prescription drugs. It is one of the primary means by which physicians, the FDA and consumers become aware of complications associated with drugs and medical devices.

193. Defendants' failure to submit and report all adverse events effectively caused the prescribing physicians, the FDA and Plaintiffs herein to be inadequately warned about the true risks of Amiodarone use for the treatment of atrial fibrillation.

194. Prescribing physicians were not adequately warned, because they received misleading "warnings" or information in addition to the FDA-approved labeling that watered down the FDA-approved labeling and rendered the overall information provided inadequate. Prescribing physicians did not know that Amiodarone was not safe to prescribe for the treatment of A-fib.

195. Defendants' Amiodarone were expected to and did reach Plaintiffs and their physicians and pharmacists without substantial change in their condition as manufactured, caused to be distributed, and sold by Defendants. Additionally, Plaintiffs' physicians prescribed, and Plaintiffs used, Amiodarone in the manner in which Amiodarone was intended to be used by Defendants, making such use reasonably foreseeable to Defendants.

196. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct and proximate result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory, special and other damages in an amount to be proven at trial.

SECOND CAUSE OF ACTION

(Negligence – Failure to Warn)

197. Plaintiffs hereby incorporate by reference all previous paragraphs, as though set forth in their entirety in this cause of action and further allege as follows.

198. At all relevant times, Defendants, and each of them, engaged in the business of designing, manufacturing, testing, marketing, labeling, causing to be distributed and/or placing into the stream of commerce Amiodarone for sale to, and use by, members of the public, including the Plaintiffs who took the drug.

199. Amiodarone posed increased risks of harm and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after the time of manufacture, distribution, and sale of Amiodarone. Defendants knew or should have known of the defective condition, characteristics, and risks associated with said product, as previously set forth herein. Defendants disregarded this increased risk of harm by failing to ensure the Medication Guide was provided to Plaintiffs; concealing from Plaintiffs and their prescribing physicians the true risks and complications of Amiodarone, including that it was not FDA approved for the treatment of A-fib, has not undergone any randomized, clinical trials for safety, and was only approved as a drug of last resort for individuals with deadly V-fib; and continuing to sell, distribute and/or defend such use of Amiodarone for the treatment of A-fib.

200. In failing to distribute the Medication Guide in the manner required by law, in failing to provide adequate warnings as required under Delaware state law, and engaging in the “off label” promotion and sale of Amiodarone for use in the treatment of A-fib that has never been approved by the FDA, Defendants failed to warn Plaintiffs of the potential risks and side effects of Amiodarone and the dangerous propensities of said medication, which risks were known or were reasonably scientifically knowable to Defendants. Defendants failed to warn the prescribing physicians of the potential risk and side effects of Amiodarone by providing false and misleading information to physicians about Amiodarone and/or concealing the true risks associated with its use. Defendants owed a duty to Plaintiffs to ensure Plaintiffs, physicians, pharmacists and the public were adequately and completely warned of all potential serious complications regarding the use of Amiodarone for the treatment of A-fib, and to ensure the Medication Guide was provided to Plaintiffs. As alleged above, Defendants knew and/or had reason to know that Amiodarone caused increased risk of harm to the Plaintiffs who took the drug for the treatment of A-fib, and other consumers like them. Defendants disregarded this increased risk of harm by failing to warn of such risks in the manner required by law; unlawfully concealing the dangerous problems associated with the use of Amiodarone; and

continuing to sell, distribute and/or defend such use of Amiodarone for the treatment of A-fib.

201. The Amiodarone ingested by Plaintiffs were expected to and did reach Plaintiffs and their physicians and pharmacists without substantial change in their condition as manufactured, caused to be distributed, and/or sold by Defendants. Additionally, Plaintiffs used Amiodarone in the manner in which Amiodarone was intended to be used by Defendants, making such use reasonably foreseeable to Defendants.

202. Further, the prescribing physicians read and relied on the PDR, Epocrates app or other prescribing reference source in prescribing Amiodarone to Plaintiffs. Teva either was or should have been aware of the statements made in those materials since, for example, Teva permitted use of pictures of its own Amiodarone pills on the Epocrates app and was under a duty to correct these materials as a form of labelling. If the information contained in the PDR, Epocrates or other reference sources had been truthful and not concealed material information, the prescribing physicians would not have prescribed Amiodarone to treat Plaintiffs' A-fib.

203. Prescribing physicians were not adequately warned, because they received misleading "warnings" or information in addition to the FDA-approved labeling that watered down the FDA-approved labeling and rendered the overall warning inadequate. Prescribing physicians did not know that Amiodarone was not safe to prescribe for A-fib. Defendants, thus, did not take the steps reasonably necessary to bring that knowledge to the attention of the medical profession.

204. As a direct and proximate result of Defendants' manufacture, promotion, distribution, and/or sale of Amiodarone, Plaintiffs suffered the injuries, losses and damages herein described.

205. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct and proximate result, Plaintiffs expended money and will continue to expend money for medical bills and

expenses. Plaintiffs are entitled to compensatory, special and other damages in an amount to be proven at trial.

THIRD CAUSE OF ACTION

(Negligence – Marketing and Sale)

206. Plaintiffs hereby incorporate by reference all previous paragraphs, as though set forth in their entirety in this cause of action and further allege as follows as against all Defendant.:

207. Before, on, and after the date of Plaintiffs' use of Amiodarone, Defendants were or reasonably should have been aware that Amiodarone had not been approved by the FDA for the treatment of atrial fibrillation. To the contrary, because of its dangers, Amiodarone was only FDA-approved for the treatment of ventricular fibrillation as a drug of last resort after all other treatments had failed. Not only was Amiodarone marketed in an "off-label" manner, but also was marketed and sold as a "first line" drug to be used in the treatment of atrial fibrillation. Despite being unlawful to do so, Defendants, either directly or indirectly by taking advantage of the efforts of other drug manufacturers, including Wyeth, marketed, distributed and/or sold Amiodarone for the treatment of atrial fibrillation.

208. Defendants owed a duty to Plaintiffs to market, cause to be distributed and/or sell Amiodarone only for uses approved by the FDA and for uses for which it has been established as safe and efficacious, and only when provided with the mandated Medication Guide in the form required by law. As alleged above, Defendants either knew or reasonably had reason to know that Amiodarone was not approved for the treatment of atrial fibrillation and was not an appropriate first line treatment for A-fib. Defendants disregarded the risk of harm created by the marketing, distribution and/or sale of Amiodarone for these "off-label" uses without the required Medication Guide.

209. Defendants, as the later manufacturers of Amiodarone generic drugs, also owed a duty of care to Plaintiffs and other consumers of Amiodarone to ensure they marketed, caused to be distributed and/or sold Amiodarone only for approved uses and with the

legally required warnings. Instead, they were able to take advantage of the campaign to market the drug for “off-label” uses, in particular for the treatment of atrial fibrillation. This concerted and systemic effort to persuade physicians Amiodarone was not only safe and efficacious for the treatment of atrial fibrillation but also as a first line treatment has led a generation of cardiologists and other cardiac specialists to incorrectly believe Amiodarone is appropriate for the treatment of atrial fibrillation. This belief is still published through publications such as the PDR and Epocrates, as well as other on-line sources as set forth above.

210. The promotion of Amiodarone as a first-line treatment for A-fib, the polar opposite of its approved use as a drug of “last resort” to be only in grave cases of life-threatening V-fib or V-tach, created an “echo chamber” effect reinforcing the impression that Amiodarone is an appropriate treatment for A-fib, as evidenced by the wide variety of on-line sources set forth above that make such a claim, up through information on the website of the American Heart Association.

211. Defendants’ Amiodarone drugs were expected to and did reach Plaintiffs and their physicians and/or pharmacies without substantial change in their condition as manufactured, marketed, distributed and/or sold by Defendants. Additionally, Plaintiffs’ physicians prescribed Amiodarone in the manner in which Amiodarone was marketed, distributed and/or sold by Defendants, making such use reasonably foreseeable to Defendants.

212. The prescribing physicians read and relied on the PDR, Epocrates app or other prescribing reference source in prescribing Amiodarone to Plaintiffs. Teva either was or should have been aware of the statements made in those materials since, for example, Teva permitted use of pictures of its own Amiodarone pills on the Epocrates app and was under a duty to correct these materials as a form of labelling. If the information contained in the PDR, Epocrates or other reference sources had been truthful and not concealed material information, the prescribing physicians would not have prescribed Amiodarone to treat Plaintiffs’ A-fib.

213. Defendants' negligent promotion, marketing, distribution and/or sale of Amiodarone was a substantial factor in causing Plaintiffs' injuries, losses and damages, as described herein.

214. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages as described throughout this Complaint. As a direct and proximate result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory, special and other damages in an amount to be proven at trial.

FOURTH CAUSE OF ACTION

(Negligence *Per Se*)

215. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further allege as follows.

216. All Defendants owed a duty to Plaintiffs to promote, market, cause to be distributed and/or sell Amiodarone only for uses approved by the FDA and for uses for which it has been established as efficacious and with all required warning information, including the Medication Guide.

217. Defendants violated this duty by marketing, promoting, causing to be distributed and/or selling Amiodarone for uses not approved by the FDA, as well as by distributing and/or selling Amiodarone without ensuring the Medication Guide was provided to Plaintiffs in the manner required by law.

218. Negligence is presumed if the defendant has violated a statute, ordinance or regulation of a public entity. Defendants' acts and omissions, as alleged in detail above, are violations of state drug safety laws as well as various FDA regulations, all as set forth in detail above.

219. Defendants' failure to ensure the Medication Guide was provided to Plaintiffs with prescriptions of Amiodarone, and to additionally provide adequate warnings

regarding the unapproved “off-label” use of Amiodarone for the treatment of A-fib, also independently violates Delaware state law.

220. As a direct and proximate result of Defendants’ violations of both Delaware state law and various FDA regulations regarding the marketing and sale of Amiodarone as set forth in detail above, Plaintiffs suffered the injuries, losses and damages herein described as a direct and proximate result of Defendants’ wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct and proximate result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory, special and other damages in an amount to be proven at trial.

FIFTH CAUSE OF ACTION

(Strict Liability – Manufacturing Defect)

221. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further allege as follows.

222. The Amiodarone ingested by Plaintiffs and Plaintiffs’ Decedents was not reasonably safe for its intended use and was defective with respect to its manufacture, as described herein, in that the Defendant failed to comply with the FDA’s Good Manufacturing Practice for Finished Pharmaceuticals, 21 C.F.R. §211 *et. Seq.*

223. Section 211.122 of the Code of Federal Regulations requires manufacturers to ensure they have written procedures detailing the receipt, identification, storage, handling, sampling, examination and/or testing of labeling and packaging materials. The labeling and packaging materials must be representatively sampled before use in packaging or labeling of a drug product. Labeling that does not meet the required specifications must be rejected and only drugs containing labeling and packaging meeting written specifications shall be distributed.

224. Section 211.130 of the Code of Federal Regulations requires written procedures to ensure correct labels, labeling, and packaging materials are used for drug products and

such written procedures must be followed. The Defendant either failed to follow appropriate written procedures regarding the labeling of Amiodarone or fail to have the required written procedures in place to ensure such labeling is both accurate and appropriately distributed.

225. Defendant also failed to implement a safer alternative design for the delivery of the Medication Guide that would have prevented or significantly reduced the risk of the Plaintiffs' and Plaintiffs' Decedents' personal injuries and death without substantially impairing the utility of the drug, when such safer alternative design of the warnings delivery process was economically and technologically feasible at the time the product left the control of the manufacturer by the application of existing or reasonably achievable scientific knowledge. Safer alternative designs for the process of delivery of FDA-mandated warnings to the product distributors, retailers and users would include, but would not be limited to (a) single use warnings on each retail bottle, and (b) larger and more prominent labeling designed to call the Medication Guide requirement to the attention of distributors and retailers.

226. The Medication Guide is part of Amiodarone's labeling. The Defendant's failure to ensure the Medication Guides were properly printed, affixed, distributed, and received are in violation of the FDA's Good Manufacturing Practices regarding Packaging and Labeling Control.

227. The Amiodarone sold by the Defendant is inherently dangerous and defective, unfit and unsafe for foreseeable uses and does not meet the expectations of consumers and health care providers.

228. Failing to Comply with the Good Manufacturing Practices set forth in 21 C.F.R. §211 regarding the manufacture, processing, packing or holding of a drug renders the drug adulterated under Section 501(a)(2)(B) of the Food, Drug & Cosmetic Act.

229. In addition, the Defendant's failure to manufacture the Amiodarone ingested by Plaintiffs and Plaintiffs' Decedents in conformity with the current Good Manufacturing Practices renders the Amiodarone an adulterated drug under Section 3302 of the

Delaware Health and Safety Food and Drug Code. Under Delaware law, it is unlawful to manufacture, sell, deliver, hold or offer for sale any drug that is adulterated. 16 Del. Code 1953 § 3302.

230. As a direct and proximate result of the Defendant's defective manufacture of Amiodarone, Plaintiffs and Plaintiffs' Decedents were severely injured including, severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and consortium, economic loss and damages including, but not limited to medical expenses, lost income, and other damages. Plaintiffs and Personal Representatives of the Decedents' Estates, are entitled to compensatory, special, and other damages in an amount to be proven at trial.

SIXTH CAUSE OF ACTION

(Fraud and Deceit)

231. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further allege as follows:

232. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, cause to be distributed and/or sell Amiodarone, owed a duty to provide accurate and complete information to Plaintiffs, their physicians, their pharmacists and the public regarding Amiodarone, including, but not limited to, ensure the distribution of the Medication Guide to all Plaintiffs who ingested Amiodarone sold by Defendants.

233. However, as set forth above Defendants either directly or by taking advantage of the information disseminated by other Amiodarone manufacturers that it did not correct, misled Plaintiffs, Plaintiffs' physicians, pharmacists and the public into believing that Amiodarone was safe and effective for use in the treatment of atrial fibrillation, and engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals and patients to use Amiodarone as set forth above even though they knew or reasonably should have known that Amiodarone was unreasonably unsafe for the treatment of A-fib and had only been approved by the FDA

as a last resort treatment for V-fib. Defendants also failed to properly warn health care professionals and the public about the safety risks of Amiodarone for the treatment of A-fib by failing to concomitantly ensure distribution of the Medication Guide to all Plaintiffs who ingested Amiodarone sold by Defendants in the manner required by law.

234. Defendants actively concealed, failed to disclose, misstated, downplayed and/or understated the health hazards and risks associated with the use of Amiodarone for the treatment of A-fib that they were under a duty to disclose based on the materiality of this information in terms of its unauthorized and unsafe use for an unapproved treatment and the resulting side effects attributable to such use. Defendants, by omitting and keeping such material facts from disclosure, deceived potential treating physicians, Plaintiffs, other patients, and the general public regarding the lack of approval of Amiodarone for sale in terms of its unauthorized “off-label” use for the treatment of A-fib, and the significant safety issues resulting from such unauthorized use particularly when unaccompanied with the required Medication Guide. These facts go directly to the safety and lack of efficacy of the use of Amiodarone for the treatment of A-fib, making such undisclosed facts presumptively material.

235. Defendants took affirmative steps to prevent the discovery and dissemination of significant evidence on the increased likelihood of injury from Amiodarone in terms of its “off-label” use for the treatment of A-fib. Defendants possessed evidence demonstrating Amiodarone caused serious adverse side effects in connection with the treatment of A-fib. Defendants failed to report all of these adverse events to the FDA and to the public, including using AERS to do so. The reporting of such adverse events is one of the primary methods by which prescribing physicians, the public and the FDA become aware of any safety or efficacy issues associated with a prescription drug. Instead, Defendants continued to sell Amiodarone by omitting the disclosure of such material facts in their possession that they had a duty and were obligated to disclose.

236. Defendants did not accurately report the results of numerous adverse events by withholding from the FDA, physicians, pharmacists, Plaintiffs, and the public, the truth

regarding the pervasive nature of Amiodarone's side effects that had been reported to them. Defendants and/or their co-conspirators received reports of Amiodarone's side effects attributable to "off-label" use from various sources yet withheld this information and maintained it in their possession, while continuing to sell Amiodarone to individuals such as Plaintiffs, as well as without ensuring distribution of the mandated Medication Guide to Plaintiffs. Defendants thus did not reveal and instead actively concealed their knowledge of numerous and serious complications with Amiodarone in connection with its use for the treatment of A-fib. Despite their knowledge of these serious problems with Amiodarone, Defendants continued and continue to market and/or sell Amiodarone nationwide.

237. Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of Amiodarone. Defendants failed to fully inform physicians, patients, including Plaintiffs, and the public, of the true defects in Amiodarone, which were known to Defendants, and continue to sell Amiodarone despite knowledge of these risk. Among other things, Defendants provided or failed to correct false and misleading information about the indications and uses of Amiodarone provided to physicians via reference materials like the PDR and Epocrates, that are used by physicians in prescribing situations and which the prescribing physicians read and rely on in prescribing Amiodarone to Plaintiffs. Teva either was or should have been aware of the statements made in those materials since, for example, Teva permitted use of pictures of its own Amiodarone pills on the Epocrates app and was under a duty to correct these materials as a form of labelling. If not for the concealment of material facts and the misleading information contained in the PDR, Epocrates or other reference sources, the prescribing physicians would not have prescribed Amiodarone to treat Plaintiffs' A-fib.

238. Defendants also concealed from Plaintiffs and Plaintiffs' physicians and pharmacists material facts they were obligated and had a duty to disclose, including that Amiodarone was not approved by the FDA for the treatment of atrial fibrillation, was not an appropriate "first line of treatment" for atrial fibrillation, was never tested in terms of

its effects on the primary demographic who took this medication (persons 65 and over), is required to be accompanied by a Medication Guide intended to warn the consumer of the serious, life-threatening complications from the use of Amiodarone, and had only be approved by the FDA for an extremely limited use without ever having conducted any clinical trials establishing the safety and efficacy of the drug, and specifically never in terms of its use for the treatment of A-fib.

239. Defendants engaged in all the acts and omissions described above with the intent that Plaintiffs and/or their physicians or pharmacists would reasonably would rely on the such material facts in deciding to prescribe and/or use Amiodarone.

240. Plaintiffs and/or Plaintiffs' physicians and pharmacists justifiably relied to Plaintiffs' detriment on Defendants' misrepresentations and/or omissions of material fact as set forth above. This reliance proximately caused the injuries and damages described in this Complaint.

241. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, economic losses and other damages. As a direct result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory, special and exemplary damages in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION

(Wrongful Death)

(Against All Defendants by the Decedent Plaintiffs)

242. The "Decedent Plaintiffs" (Plaintiffs Marchette Cook, Vernon Deboard, Carolyn Harrison, Mark Laganelli, Doyle Turner, and Albert Shepherd) incorporate by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further allege as follows.

243. The Decedent Plaintiffs are the surviving heirs of the persons listed above who used Defendants' Amiodarone products and died as a proximate result ("Decedents").

Said Decedents were prescribed, supplied with, received and ingested Amiodarone that was placed in the stream of commerce by Defendants.

244. The injuries and death of Decedents was caused by the wrongful acts, omissions and misrepresentations of Defendants as set forth above.

245. As a result of the conduct of Defendants and their ingestion of Amiodarone, the Decedents suffered fatal injuries.

246. As a result of the deaths of their relatives, the Decedent Plaintiffs were also deprived of the love, companionship, comfort, support, affection, society, solace and moral support of these Decedents.

247. The Decedent Plaintiffs are entitled to recover economic and non-economic damages against all Defendants for wrongful death directly and legally caused by the wrongful acts, omissions and misrepresentations of Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows, as appropriate and applicable for the particular causes of action set forth above:

1. For general (non-economic) and exemplary damages proportionate thereto according to proof at the time of trial;
2. For special (economic) and exemplary damages proportionate thereto according to proof at the time of trial;
3. For restitution and restitutionary disgorgement of all revenues or profits that Defendants have obtained through design, promotion, marketing, manufacture, distribution and/or sale of Amiodarone;
4. For pre-judgment and post-judgment interest as permitted by law;
5. For costs of suit incurred herein as permitted by law, including attorneys' fees pursuant to the claims that expressly or relatedly permit such an award;
6. For injunctive relief including, but not limited to, prohibiting Defendants from selling Amiodarone without also distributing the Medication Guide in the manner required by law;

7. For such other and further relief as this Court may deem proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all claims so triable.

DATED: November 12, 2019

/s/ Raeann Warner

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